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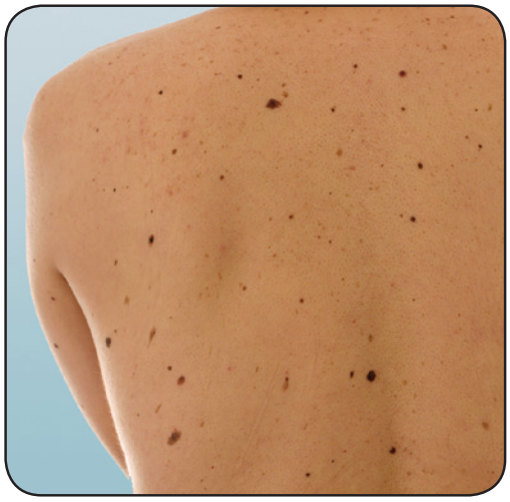
JDPA

Journal of Dermatology for Physician Assistants



Official Journal of the Society of Dermatology Physician Assistants

BRIEF SUMMARY OF PRESCRIBING INFORMATION

This Brief Summary does not include all the information needed to use JUBLIA safely and effectively. See full prescribing information for JUBLIA.

JUBLIA® (efinaconazole) topical solution, 10%

For topical use
Initial U.S. Approval: 2014

INDICATIONS AND USAGE

JUBLIA (efinaconazole) topical solution, 10% is an azole antifungal indicated for the topical treatment of onychomycosis of the toenail(s) due to *Trichophyton rubrum* and *Trichophyton mentagrophytes*.

DOSAGE AND ADMINISTRATION

Apply JUBLIA to affected toenails once daily for 48 weeks, using the integrated flow-through brush applicator. When applying JUBLIA, ensure the toenail, the toenail folds, toenail bed, hyponychium, and the undersurface of the toenail plate, are completely covered.

JUBLIA is for topical use only and not for oral, ophthalmic, or intravaginal use.

CONTRAINDICATIONS

None.

ADVERSE REACTIONS

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

In two clinical trials, 1227 subjects were treated with JUBLIA, 1161 for at least 24 weeks and 780 for 48 weeks. Adverse reactions reported within 48 weeks of treatment and in at least 1% of subjects treated with JUBLIA and those reported in subjects treated with the vehicle are presented in Table 1.

Table 1: Adverse Reactions Reported by at Least 1% of Subjects Treated for up to 48 Weeks

Adverse Event, n (%)	JUBLIA N = 1227	Vehicle N = 413
Ingrown toenail	28 (2.3%)	3 (0.7%)
Application site dermatitis	27 (2.2%)	1 (0.2%)
Application site vesicles	20 (1.6%)	0 (0.0%)
Application site pain	13 (1.1%)	1 (0.2%)

DRUG INTERACTIONS

In vitro studies have shown that JUBLIA, at therapeutic concentrations, neither inhibits nor induces cytochrome P450 (CYP450) enzymes.

USE IN SPECIFIC POPULATIONS

Pregnancy

Pregnancy Category C

There are no adequate and well-controlled studies with JUBLIA in pregnant women. JUBLIA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Systemic embryofetal development studies were conducted in rats and rabbits. Subcutaneous doses of 2, 10 and 50 mg/kg/day efinaconazole were administered during the period of organogenesis (gestational days 6-16) to pregnant female rats. In the presence of maternal toxicity, embryofetal toxicity (increased embryofetal deaths, decreased number of live fetuses, and placental effects) was noted at 50 mg/kg/day [559 times the Maximum Recommended Human Dose (MRHD) based on Area Under the Curve (AUC) comparisons]. No embryofetal toxicity was noted at 10 mg/kg/day (112 times the MRHD based on AUC comparisons). No malformations were observed at 50 mg/kg/day (559 times the MRHD based on AUC comparisons).

Subcutaneous doses of 1, 5, and 10 mg/kg/day efinaconazole were administered during the period of organogenesis (gestational days 6-19) to pregnant female rabbits. In the presence of maternal toxicity, there was no embryofetal toxicity or malformations at 10 mg/kg/day (154 times the MRHD based on AUC comparisons).

In a pre- and post-natal development study in rats, subcutaneous doses of 1, 5 and 25 mg/kg/day efinaconazole were administered from the beginning of organogenesis (gestation day 6) through the end of lactation (lactation day 20). In the presence of maternal toxicity, embryofetal toxicity (increased prenatal pup mortality, reduced live litter sizes and increased postnatal pup mortality) was noted at 25 mg/kg/day. No embryofetal toxicity was noted at 5 mg/kg/day (17 times the MRHD based on AUC comparisons). No effects on postnatal development were noted at 25 mg/kg/day (89 times the MRHD based on AUC comparisons).

Nursing Mothers

It is not known whether efinaconazole is excreted in human milk. After repeated subcutaneous administration, efinaconazole was detected in milk of nursing rats. Because many drugs are excreted in human milk, caution should be exercised when JUBLIA is administered to nursing women.

Pediatric Use

Safety and effectiveness of JUBLIA in pediatric subjects have not been established.

Geriatric Use

Of the total number of subjects in clinical trials of JUBLIA, 11.3% were 65 and over, while none were 75 and over. No overall differences in safety and effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and the younger subjects, but greater sensitivity of some older individuals cannot be ruled out.

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility

A 2-year dermal carcinogenicity study in mice was conducted with daily topical administration of 3%, 10% and 30% efinaconazole solution. Severe irritation was noted at the treatment site in all dose groups, which was attributed to the vehicle and confounded the interpretation of skin effects by efinaconazole. The high dose group was terminated at week 34 due to severe skin reactions. No drug-related neoplasms were noted at doses up to 10% efinaconazole solution (248 times the MRHD based on AUC comparisons).

Efinaconazole revealed no evidence of mutagenic or clastogenic potential based on the results of two in vitro genotoxicity tests (Ames assay and Chinese hamster lung cell chromosome aberration assay) and one in vivo genotoxicity test (mouse peripheral reticulocyte micronucleus assay).

No effects on fertility were observed in male and female rats that were administered subcutaneous doses up to 25 mg/kg/day efinaconazole (279 times the MRHD based on AUC comparisons) prior to and during early pregnancy. Efinaconazole delayed the estrous cycle in females at 25 mg/kg/day but not at 5 mg/kg/day (56 times MRHD based on AUC comparisons).

PATIENT COUNSELING INFORMATION

See FDA-Approved Patient Labeling (Patient Information).

VALEANT
Pharmaceuticals North America LLC

Manufactured for:
Valeant Pharmaceuticals North America LLC, Bridgewater, NJ 08807 USA

Manufactured by:
Valeant Pharmaceuticals International, Inc., Laval, Quebec H7L 4A8, Canada

U.S. Patents 8,039,494; 7,214,506

Based on 9462903 JUB.0130.USA.16 Issued: 09/2016

ONYCHOMYCOSIS*

Your patient's dirty secret?

TIME TO CLEAN IT UP

AT THE SITE OF INFECTION[1]

JUBLIA®
(efinaconazole)
Topical Solution 10%

*For the treatment of onychomycosis of the toenail(s) due to *Trichophyton rubrum* and *Trichophyton mentagrophytes.*

JUBLIA allows some patients to have clearer toenails grow back.[1] Individual results may vary.

№1
PRESCRIBED BRAND FOR TOENAIL FUNGUS[2]

INDICATION

JUBLIA (efinaconazole) topical solution, 10% is indicated for the topical treatment of onychomycosis (tinea unguium) of the toenail(s) due to *Trichophyton rubrum* and *Trichophyton mentagrophytes.*

IMPORTANT SAFETY INFORMATION

- JUBLIA is for topical use only and is not for oral, ophthalmic, or intravaginal use.
- Patients should be instructed to contact their health care professional if a reaction suggesting sensitivity or severe irritation occurs.
- The most common adverse reactions (incidence >1%) were (vs vehicle): ingrown toenail (2.3% vs 0.7%), application-site dermatitis (2.2% vs 0.2%), application-site vesicles (1.6% vs 0%), and application-site pain (1.1% vs 0.2%).
- JUBLIA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus, and should be used with caution in nursing women. The safety and effectiveness in pediatric patients have not been established.

To report SUSPECTED ADVERSE REACTIONS contact Valeant Pharmaceuticals North America LLC at 1-800-321-4576 or FDA at 1-800-FDA-1088 or visit www.fda.gov/medwatch.

Please see Brief Summary of full Prescribing Information on the adjacent page.

Find out more by visiting **www.JubliaRx.com.**

References: 1. JUBLIA [prescribing information]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; 2016. **2.** Toenail fungus market summary—current 12 week TRx count: April 2017. Symphony Health Solutions Integrated Dataverse.

JDPA Journal of Dermatology for Physician Assistants

EDITORIAL MISSION: The JDPA is the official clinical journal of the Society of Dermatology Physician Assistants. The mission of the JDPA is to improve dermatological patient care by publishing the most innovative, timely, practice-proven educational information available for the physician assistant profession.

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THIS ISSUE: The JDPA includes articles that have been reviewed and approved for Category I (Preapproved) CME credit by the American Academy of Physician Assistants. Approval is valid for 1 year from the issue date, and participants may submit the self-assessment at any time during that period. Category I CME articles included in JDPA are planned and developed in accordance with AAPA's CME Standards for Journal Articles and for Commercial Support of Journal Articles.

GOING GREEN: Since its inception, the JDPA has utilized eco-friendly printing practices. The JDPA is printed on paper obtained from sustainable forests that meet strict environmental standards. Soy-based inks that have a low environmental impact are used during printing of the journal and the journal is printed using 100% renewable energy. SDPA members may join us in our efforts and opt to receive the JDPA in digital format.

PUBLISHING STAFF

Managing Editor Jennifer M. Hayden, M.Ed
Copy Editor Douglas Morris
Art Director Angela Simiele
Website Design Terry Scanlon

SALES OFFICE

Physician Assistant Communications, LLC
P.O. Box 416, Manlius NY 13104-0416
Phone (315) 663-4147
PAC@pacommunications.org
www.pacommunications.org

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POSTMASTER: Send address changes to Society of Dermatology Physician Assistants, Inc., 8400 Westpark Drive, 2nd Floor, McLean, VA 22102 1-800-380-3992., email SDPA@dermpa.org, www.dermpa.org.

Changing Landscape and Seasons

In upstate New York the hot topic of conversation is usually the weather. You can count on several patients a day (or more) in clinic talking about the weather. Around here, winter tends to last a bit longer than most people prefer. School delays and messy morning commutes that spill over into the springtime seem to become less and less tolerated, even for this part of the country. People typically are ready for the warmer weather of spring and all that comes with it much sooner than it actually arrives. If we pause to think about it, weathering through more challenging and longer lasting winters should prepare us to be more appreciative and grateful for all of the beauty and new growth when spring finally does arrive. Holding on to the hope that more pleasant weather is around the corner does seem to help when the chill of winter lingers well past its welcome.

Recently, the PA profession has weathered some major storms. These were not easy or pleasant issues to have to wade through. Our SDPA leaders have been behind the scenes working diligently to defend our profession. They have spoken about the hard work, quality care, and dedication that our members provide day in and day out to their patients and communities. They have educated others on our important role as PAs within the dermatology healthcare community. Our SDPA leaders have tackled these issues for our Society, for our profession, for us, and ultimately for our patients. They have dedicated time outside of their clinic hours and time away from their families. Their focus and attention to these crucial issues will help us all to be better understood and respected for what we do as dermatology PAs. Thank you to the outgoing, current, and new leaders of the SDPA. Thank you for your time, attention, and care given to strengthening our profession. Thank you for weathering the winter storms so that we may come out stronger and with continued new growth for our Society and our profession. Thank you for not letting go of hope and believing that you can and will make a difference.

Travis Hayden, MPAS, PA-C
JDPA Editor in Chief
editor@jdpa.org

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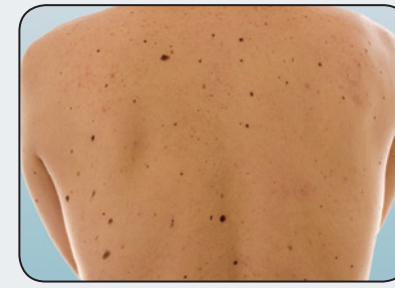

DEPARTMENTS

Ortho | Dermatologics

GIVES BACK

By supporting charitable programs that serve providers and patients, we strive to build meaningful connections within the dermatology community

Camp Discovery

Helping children with chronic skin conditions enjoy a week of fun

Aspire Higher™

Helping students, including working mothers, to receive a scholarship to pursue higher education

Passion to Heal®

Sponsoring medical professionals to help children in developing countries

1:1 Derm connections

Connect with us to make a difference.
To learn more about these programs,
visit **ortho-dermatologics.com/philanthropy**

Ortho | Dermatologics

CALENDAR OF EVENTS

2018

JUNE
SDPA Summer Dermatology Conference
June 27 – July 1, 2018
The Westin Seattle
Seattle, WA

JULY
AAD Summer Meeting
July 26 - 29, 2018
Chicago, IL

NOVEMBER
SDPA 16th Annual Fall Dermatology Conference
November 1 - 4, 2018
Loews Portofino Bay Hotel
Orlando, FL

Empower. Educate. Advance.
The Future of Dermatology

FROM THE SDPA
NEWS & CURRENT AFFAIRS

It is hard to believe my year as President of the SDPA is quickly coming to a close. I want to sincerely thank all of you for the hard work and dedication to dermatology PAs and this great organization. Whatever you did this year to advance dermatology PAs, be proud. It was a challenging year with attacks on our profession coming from unexpected places, not to mention unexpected hurricanes. However, by working together we joined forces to face the attacks and challenges head on. There were many good things this year as well, including the launch of the next phase of the Diplomate fellowship, a meeting with the AAD Board, legislative wins for PAs as a whole, and the hosting of our first PA reception at the AAD conference. It all added up to progress.

Beyond the progress that was made this year, let's turn our thoughts to the purpose and focus that will be required of us all in the year ahead.

Given the recent attacks on dermatology PAs and the continued need for optimal team practice, it will take all of us to make strides to protect our profession. We are the ones that must defend our profession, for if we don't, who will?

It has been an incredibly rewarding year serving as your President. I have greatly enjoyed getting to meet dermatology PAs from all over the country and discussing the challenges and the joys we face together. It was a privilege to get to meet with lawmakers on Capitol Hill and advocate for PAs. It was startling for me to learn that PAs give the lowest amount to our PA Political Action Committee (PAC) compared to our physician and NP colleagues. Giving back is more important than ever. Whether it's volunteering a few hours a month on a committee, or donating to the DPAF or AAPA's PAC, it is these acts that will propel us forward. Now is not the time to become apathetic. Now is the time to get involved and give of our talents to ensure our profession continues to be the great profession we all love.

Jane Mast, MPAS, PA-C
SDPA President

SUPER EARLY BIRD RATE $149 / OCT 1 - FEB 1

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Come Celebrate Our 10th Anniversary.

This program is not yet approved for CME Credit. Conference organizers plan to request maximum of 27 hours (21maximum earnable by any attendee) of Category I CME Credit from AAPA.

We look forward to seeing you in Atlanta!

Dermatology Market Watch

Dermatology Pa Foundation Presents The Mental Health Comorbidities Of Psoriasis

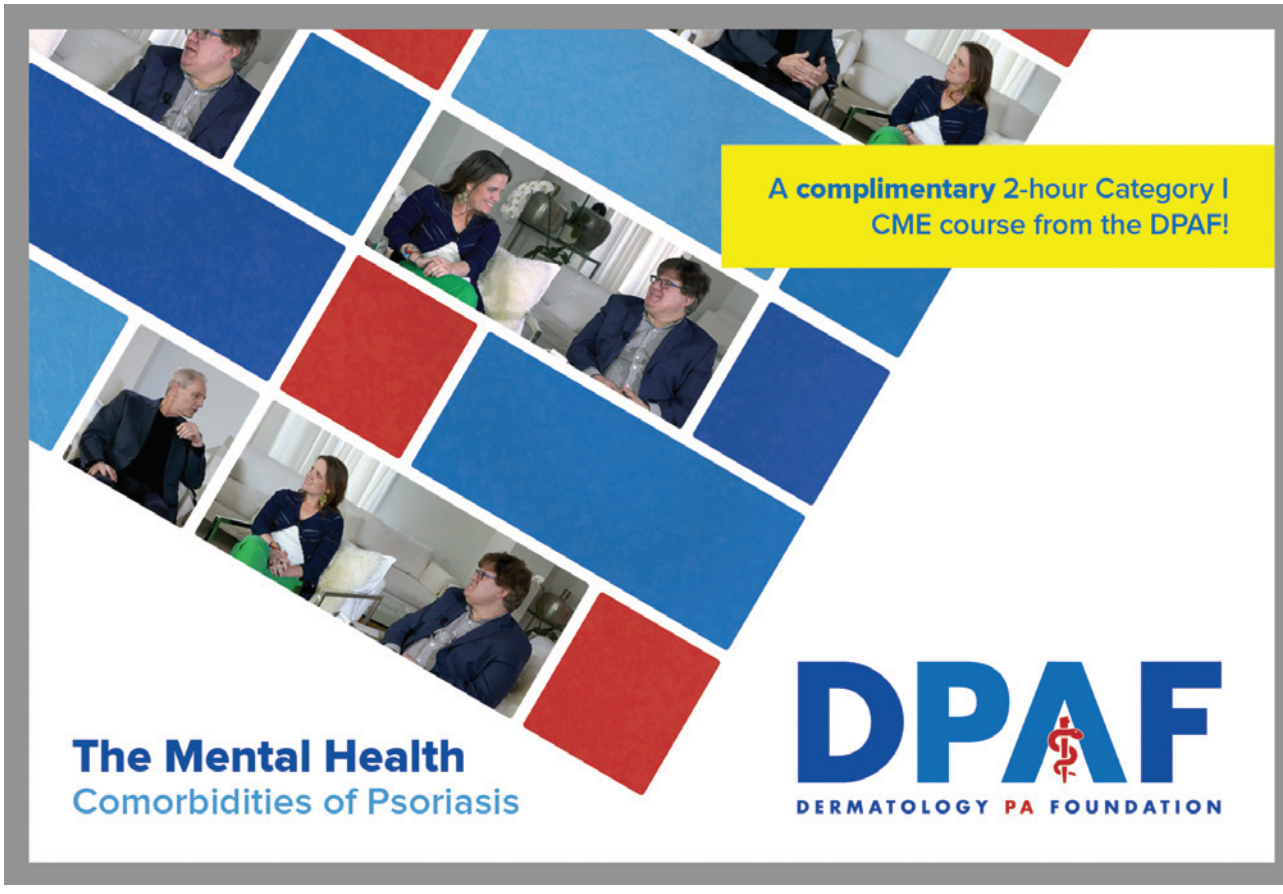
A Free 2-Hour Category I Cme Course

The Mental Health Comorbidities of Psoriasis is a special complimentary course brought to you by The DPAF. Join Dr. Richard Fried, Bethany Grubb, MPAS, PA-C, and Dr. Jeffrey Weinberg for this unique learning experience with a more conversational tone between these three industry experts outside of a conference setting. This course will be available until April 1, 2020. After completing this course participants will have increased knowledge of how to recognize, identify and assess mental health comorbidities in psoriatic patients, screening tools, an appropriate plan of action, and more. Participants will earn 2 AAPA Category I CME credits for completion of this course. Participants will watch two 1-hour discussions (Part 1 and Part 2) between our faculty, each followed by a course exam.

After completing this activity, participants should be able to:

1. Recognize, identify, and assess mental health comorbidities in psoriatic patients
2. Identify screening tools that can be utilized in the office
3. Identify a plan of action in the management of a patient who is clinically depressed
4. Identify a plan of action in the management of a patient who reveals suicidal ideations or a suicide plan
5. Summarize evidence-based recommendations for treating psoriasis
6. Review evidence on new therapeutic strategies that may further improve outcomes in patients with psoriasis

This course is available through the SDPA's Online Learning Center for easy access by both SDPA members and non-members. To get started, simply log onto the SDPA Learning Center and search for the course under the "Course Catalog" tab. The DPAF will be working to provide education courses each year, so stay tuned.



Encore Dermatology Announces the Launch of Impoyz™

A newly formulated high-potency topical corticosteroid cream (clobetasol propionate 0.025%)

Encore Dermatology Inc. recently announced the availability of a new topical product, Impoyz cream, indicated for the treatment of moderate to severe plaque psoriasis in patients 18 years of age or older. Impoyz cream is the only FDA-approved high-potency topical corticosteroid with 0.025% clobetasol propionate.

For over 30 years, clobetasol propionate has been available in only one strength. "Now we are especially excited to launch Impoyz cream, as it offers dermatology providers with their first new strength as an alternative to traditional clobetasol – allowing providers to treat their patients with a lower concentration," said Bob Moccia, president and CEO of Encore Dermatology.

Impoyz cream contains clobetasol propionate 0.025% in a modern vehicle. This specially formulated product is effective in reducing the signs and symptoms of plaque psoriasis while offering a favorable tolerability and safety profile. The active ingredient in Impoyz, clobetasol propionate, is one of the most widely used corticosteroids for the treatment of psoriasis.

"Psoriasis patients are some of the most challenging to treat because of the chronic nature of the disease and the effect it has on their quality of life," said Mark Lebwohl, MD, Professor and Chairman of the Kimberly and Eric J. Waldman Department of Dermatology at the Icahn school of Medicine at Mount Sinai. "Impoyz cream gives dermatology providers the opportunity to treat moderate to severe psoriasis patients with an active ingredient they know well in a new, modern formulation."

Encore Dermatology is dedicated to offering a wide variety of dermatology products to aid providers in managing the patients they see most. According to Mr. Moccia, the addition of Impoyz cream is an important milestone for Encore Dermatology, as it is the first of what the company hopes will be many new drug application (NDA) products Encore plans to launch.

Impoyz cream is available in the U.S. by prescription only in a 60g tube.

Certification Review

All Those Things Inside the Skin You Might Have Forgotten

By James A. Van Rhee, MS, PA-C

Are you recertifying soon? Start your board review early. Each issue of the JDPA features one board question accompanied by a brief explanation of the answer along with any pertinent test taking tips. Best of luck!

QUESTION: A 65-year-old male presents with fatigue, weakness, and a 10-pound weight loss over the past six months. On physical examination no lymphadenopathy or splenomegaly is noted. Laboratory testing reveals the following:

TEST	VALUE	Normal Range
WBC	13,500	4,800-10,500/mm3
RBC	3.7	4.5-5.5 M/microL
HGB	11.8	14-18 g/dL
HCT	34	40-54 %
MCV	91	80-100 fL
MCHC	35	32-36 %
PLT	186,000	150,000-450,000/mm^3
BUN	30	10-20 mg/dL
Creatinine	1.9	0.6-1.3 mg/dL
Total Protein	11.3	6.0-9.0 g/dL
Albumin	4.0	3.5-5/0 g/dL
Calcium	10.9	8.5-10.5 mg/dL
Phosphorus	4.0	2.2-4.8 mg/dL

Which of the following is the most likely diagnosis?

A. Multiple myeloma
B. Hodgkin's lymphoma
C. Chronic myeloid leukemia
D. Immune thrombocytopenia purpura

EXPLANATION: Multiple myeloma is most commonly noted in elderly patients and presents with bone pain and nonspecific symptoms. Lymphadenopathy and splenomegaly are not noted. Laboratory studies reveal a normocytic, normochromic anemia, elevated total protein with elevation in globulin level; renal insufficiency and hypercalcemia are also common. Hodgkin's lymphoma presents with fever, weight loss, and night sweats. On physical examination lymphadenopathy is noted. Laboratory studies reveal anemia, but total protein and calcium are normal. Chronic myeloid leukemia is commonly noted in middle-aged patients and presents most commonly with splenomegaly. Laboratory studies reveal markedly elevated white blood cell counts, typically greater than 150,000/mm3. Immune thrombocytopenia purpura presents with bruising and bleeding. Laboratory testing reveals a platelet count less than 150,000/mm^3.

The correct answer is A.

James A. Van Rhee, MS, PA-C, is the Program Director for the Yale University School of Medicine Physician Assistant Program. Mr. Van Rhee has been involved in physician assistant education for over 20 years. He has served as project director and test item writer for the Physician Assistant Education Association's (PAEA) Physician Assistant Clinical Knowledge Rating Assessment Tool (PACKRAT) and is the author of the Physician Assistant: Certification and Re-certification Review Book, published by Elsevier. For the last fifteen years he has been course director and presenter of the Physician Assistant Board Review, which is now being produced live online by Kaplan Medical.

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SOCIETY OF DERMATOLOGY PHYSICIAN ASSISTANTS
SDPA
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Dysplastic Nevus Syndrome: A Case Report

By Katherine Edelen, MS, PA-C and Alicia Elam, PharmD

Dysplastic nevus syndrome (DNS), also known as atypical mole syndrome, is a pigmented cutaneous disorder that is characterized by the presence of multiple dysplastic nevi and associated with an increased risk of melanoma.[1] Studies have shown that the frequency of melanoma arising in these "nevi with atypical disorder" is somewhere between 10 to 40%, and that the grade of severity is directly related to risk, overall.[2] Melanoma is responsible for 80% of deaths related to skin cancer and because dysplastic nevi put one at risk for melanoma development, it is crucial to identify those who are affected appropriately. Patients presenting with multiple dysplastic nevi warrant complete dermatological examination and surveillance to detect melanocytic changes early, as well as surgical intervention, when necessary, to ultimately improve the management and prognosis of dysplastic nevi and melanoma.[1] Often times DNS and familial atypical multiple mole melanoma (FAMMM) syndrome are used interchangeably. Both terms are characterized by a large number of dysplastic nevi. The actual difference between the two is that "dysplastic nevus syndrome" is a diagnosis that describes "sporadic (nonfamilial) melanoma," while "familial atypical multiple mole and melanoma syndrome" is a phenotypic expression characterized by hereditary melanoma.[3]

» CME

This program has been reviewed and is approved for a maximum of .5 hours of AAPA Category I CME credit by the Physician Assistant Review Panel.

Approval is valid for 1 year from the issue date of June 2018. Participants may submit the self-assessment exam at any time during that period.

This program was planned in accordance with AAPA's CME Standards for Enduring Material Programs and for Commercial Support of Enduring Material Programs.

SDPA members may access the posttest at www.jdpa.org

Learning Objectives:

1) Understand the difference between dysplastic nevus syndrome (DNS) and Familial atypical multiple mole melanoma (FAMMM) syndrome.

2) Know how to distinguish (or say know the difference between) between atypical nevi and common acquired nevi.

3) Describe the typical presentation of dysplastic nevi.

4) Know the current recommended screening tools for the prevention of melanoma and the importance of early detection and diagnosis of dysplastic nevi.

INTRODUCTION

Melanoma is the 5th leading cause of cancer in men and the 7th leading cause of cancer in women causing significant morbidity and mortality.[4] Consequently, emphasis on the importance of screening at-risk patients is critical to provide early diagnosis, appropriate care, and follow up.[3] The purpose of this case report is to show the importance of identifying patients with dysplastic nevus syndrome and to introduce techniques and interventions commonly utilized in the management of their care.

Based on reported findings, many believe that FAMMM syndrome is autosomal dominant and has been linked to chromosome 9p21. The affected gene is a cell cycle regulator, CDKN2A, which encodes p16, a tumor suppressor protein. It is believed that when this protein becomes mutated, it expedites abnormal cell proliferation.[5] In addition to increasing one's risk of melanoma, data has shown that the CDKN2A mutation also increases one's risk of pancreatic cancer.3 Sporadic cases of the nonfamilial version of this syndrome have also been observed in which there is no apparent family history.[1]

A considerable finding in distinguishing between atypical nevi and common acquired nevi is the natural history of lesions regarding the specific time in one's life that they begin to appear. Dysplastic nevi usually do not appear until puberty and generally develop throughout one's lifetime. Acquired nevi, in contrast, first begin to appear after the age of six months and reach a maximum count during the third decade.[3] On

physical examination, nevi can vary in size but those measuring greater than 5mm are more suggestive of a dysplastic nevus when compared to a common acquired nevus. More commonly, dysplastic nevi are localized to the trunk, as opposed to the extremities, but can ultimately develop anywhere on the body. Dysplastic nevi are macular and asymmetric in nature and are generally characterized by irregular borders. These particular lesions may be associated with erythema and have been reported to sometimes have an "eczematous halo." Dysplastic nevi vary in color, ranging from shades of tan and brown and are frequently associated with a pinkish background.[5]

In this case report, we present a 24 year-old female patient with multiple dysplastic nevi located sporadically along her trunk, in which several are suspicious for dysplastic features. She has not had a prior history of melanoma or a diagnosis of dysplastic nevus syndrome in the past.

CASE PRESENTATION

A 24 year-old Caucasian female presents to clinic with a five year history of noticing multiple new nevi appearing on her abdomen and back. Her primary concern is that some of the nevi were evolving with regard to shape and color and wanted to confirm that they were not cancerous. Her past medical history is unremarkable. Based on her dermatological exam, she exhibits the clinical characteristics of dysplastic nevus syndrome; for example, there is at least 50 dysplastic nevi sporadically located on her abdomen, lower back, and posterior chest. Some nevi are greater than 5mm in width and displayed asymmetry, atypical borders, and discoloration (see below). The patient has no family history of melanoma but she reports that her father has several "dysplastic nevi" located on his back and abdomen.

Pathological analysis of five shave biopsies from the patient's lower back and chest revealed one melanoma in-situ and four severely dysplastic nevi. Subsequently, the patient was scheduled for surgery in which all lesions were re-excised with elliptical excisions and the margins were checked for clearance.

DISCUSSION

While clinical evaluation and medical management are crucial aspects of care for dysplastic nevi, patient education is a critical component, as well.[3] As mentioned earlier, the presence of dysplastic nevi is a major risk factor for the development of melanoma; therefore, routine skin examinations and risk assessments are crucial components in preventing the development of melanoma as well as to provide early diagnosis.[3] Unfortunately, there is a shortage of evidence regarding how frequently patients with dysplastic nevi should be monitored, but the decision is generally dependent upon the patient's individual risk factors and clinical characteristics, such as those with atypical mole syndrome. Frequency of follow up should depend on the number of dysplastic nevi as well as the degree of atypical disorder seen with pathological review.[6] In addition, some literature suggests that the frequency of follow-up cutaneous examinations should also be based on the patient's family history of melanoma. Therefore, recommendations may advocate that patients with dysplastic nevi and a positive family history of melanoma be evaluated every three to six months, and with a follow up of every six to twelve months for those dysplastic nevus patients without a family history of melanoma.[6] Other measures such as cutaneous biopsies and excisions may also be considered depending on the clinician's suspicion of questionable lesions.[3]

During the work up, a number of different techniques and interventions can be utilized to aid in the diagnosis of dysplastic nevi. Dermoscopy is a noninvasive technique used by dermatology providers in examining pigmented skin lesions. This technique is inexpensive, easy to use, and allows visualization of structures that are unable to be seen with only the naked eye.[7] The diagnosis of a dysplastic nevus is traditionally a clinical decision, therefore dermoscopy is not always necessary, but may be beneficial when differentiating between a dysplastic lesion and a benign lesion.[3] In addition, clinicians commonly utilize the well-known ABCDE method to evaluate for asymmetry, abnormal borders, discoloration, and the diameter of lesions. It wasn't until more recently that an "E" was added to the ABCD acronym to emphasize the "evolution" of a lesion. Evolving lesions are those that change in size or shape or that cause changing symptoms (such as itching, tenderness, or bleeding) as well as those that are evolving in regard to the color of the lesion.[8] A study that was performed by Cassileth et al. explained how patients tend to seek medical advice due to concern for a potential melanoma presented with a group of particular symptoms. Of the reported symptoms, changes in "size, elevation, and color" were the most commonly reported. This further emphasizes the importance of evolution in the detection of an early melanoma, as opposed to a dysplastic nevus, in pigmented lesions.[8]

In cases such as the one outlined in this article, where a potential melanoma is suspected, a shave or punch biopsy may be performed to evaluate the

histological characteristics of the pigmented lesion. Based on those findings, some experts believe in excising any lesions found to be dysplatic with positive margins. This is a method of preference considering there are currently no universally accepted guidelines regarding the reexcision of dysplastic nevi at this time.[3] The grades of dysplasia as well as the margin status after biopsy are vital components in determining whether or not further surgical intervention is deemed necessary.[9] Findings suggest that patients most likely to benefit from surgical intervention have moderate-to-severe and severe dysplasia due to the increased risk of future melanoma. It is also recommended that patients with mild-to-moderate and moderate dysplasia may be observed clinically and monitored routinely.[10]

After the excisions were performed with clear margins, the patient was referred to have mole mapping performed using total body photography (TBP), which is a practice more recently utilized by dermatologists allowing identification of suspicious lesions based on the comparison of serial images. Data has shown that TBP may increase the excision threshold of practicing clinicians, which may or may not be beneficial, depending on patient compliance with follow-up. Total body photography has been identified as a noninvasive diagnostic procedure to ultimately improve sensitivity of a melanoma diagnosis while avoiding unnecessary biopsies and excisions.[11]

With regards to the pancreatic aspect of FAMMM syndrome, there are currently no routine screening practices that can be utilized to detect pancreatic cancer in affected patients, but surveillance is still warranted, especially for those with a positive family history of pancreatic cancer.[12,13]

CONCLUSION

Melanoma causes 4% of overall skin cancers, although it leads to over 80% of skin-related deaths. While dysplastic nevi are relatively benign lesions, they still potentiate the risk of having a melanoma at some point in one's lifetime, therefore emphasizing the importance of early detection and diagnosis.[1] There is evidence that simply educating and providing thorough instruction on performing self-exams and using the ABCDE method can advocate the identification of cancerous lesions such as melanoma.[8] In conclusion, sun protection education and routine monitoring with biopsy when necessary are the foundations of management for patients affected by dysplastic nevi and dysplastic nevus syndrome and treatment plans should be tailored based on each individual patient.[5]

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Katherine Edelen, MS, PA-C, *completed her Bachelor of Science at the University of Georgia in Health Promotion and Education. She completed her Masters degree in Physician Assistant Studies at Augusta University, formerly named the Medical College of Georgia, in August 2017. She has indicated no relationships to disclose relating to the content of this article.*

Alicia Elam, PharmD *is an Associate Professor at the Augusta University Physician Assistant Program, where she is the Director of the pharmacology curriculum for the program. She also serves as the Associate Director of Admissions. Dr. Elam received her Bachelor of Science degree from Bennett College in Chemistry and her Doctor of Pharmacy degree from the Mercer University Southern School of Pharmacy. She has indicated no relationships to disclose relating to the content of this article.*

From The Patient's Perspective
Living With Pemphigus Vulgaris

It all started in 2012. I had a sore on my left shoulder that didn't get any better after several weeks. As most of us do, I gave it more time. After several months, it had not improved; it had gotten bigger. I also had another sore appear on my right shoulder.

I went to see my family practice doctor, and they were not sure what it was. Long story short, after two doctors I went to the local dermatologist, who also wasn't sure what my sore was. They took a biopsy, and then another. When the results came in, I was diagnosed with pemphigus vulgaris (PV). It wasn't something I had ever heard of, and neither had my dermatologist. She recommended that I see a different dermatologist, Dr. Donna Culton at the University of North Carolina School of Medicine, who specializes in PV.

After researching online, I realized how rare PV is and that there is no cure. At my first appointment with Dr. Culton, I was terrified. But she told me that my disease could be controlled with proper medication. She also told me that there were several trial medications I could have access to through clinical trials. At first I was skeptical, but we decided on a clinical trial that we thought would benefit me the most. As luck would have it, the clinical trial started a few weeks later.

At that point, my condition had worsened. I had sores on my shoulders, back, and chest. Feelings of hopelessness had taken over, and my kids couldn't even hug me because of the sores. I was ready to try anything to get better.

I started a six-month clinical trial with an infusion, followed by additional visits to monitor my progress. After about two weeks, we started to see improvement, and I continued to improve over the following months. By the time the clinical trial had finished, the PV had almost completely cleared up. I was very happy about it.

In 2017 my PV came back worse than ever. It was all over my body, from my head and mouth all the way down to my feet. I saw Dr. Culton again. Since I had a good experience with the last clinical trial, I asked her about starting a new one. I'm now taking part in my second trial and already showing signs of improvement. I'm looking forward to the end results.

Please remember that patient participation in clinical trials assists with finding new treatment options and a potential cure.

Dr. Culton put me in contact with Marc Yale, a mucous membrane pemphigoid patient and International Pemphigus & Pemphigoid Foundation (IPPF) Executive Director. He was the first patient I had ever talked to. Marc and I talked for quite some time about our experiences. Since then, the IPPF has been a great way to learn about this condition and to get support. I strongly advise patients and caregivers to use all of the tools on the IPPF website. I wish I had known about these resources a long time ago.

Thank You,
Jeff Weisgerber

ippf International Pemphigus & Pemphigoid Foundation

The International Pemphigus & Pemphigoid Foundation (IPPF) seeks to improve the quality of life for all people affected by pemphigus and pemphigoid through early diagnosis and support. The IPPF's Annual Patient Conference focuses on connecting patients and their families to leading dermatologists and disease experts. This year's event will be held in Durham, NC on October 12-14, 2018. The conference also shows patients that they are not alone in their experiences. To learn more about the Annual Patient Conference, as well as IPPF support groups, peer support, and other resources, visit www.pemphigus.org.

International Pemphigus and Pemphigoid Foundation1331 Garden Highway, Suite 100, Sacramento, CA 95833www.pemphigus.org
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AKTIPAK™ (erythromycin and benzoyl peroxide) Gel, 3%/5% is indicated for the topical treatment of acne vulgaris.

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Contraindications: AKTIPAK™ is contraindicated in those individuals who have shown hypersensitivity to any of its components.

Precautions: For topical use only; not for ophthalmic use. Concomitant topical acne therapy should be used with caution because a possible cumulative irritancy effect may occur, especially with the use of peeling, desquamating or abrasive agents. If severe irritation develops, discontinue use and institute appropriate therapy. The use of antibiotic agents may be associated with the overgrowth of nonsusceptible organisms. If this occurs, discontinue use and take appropriate measures. Avoid contact with eyes and all mucous membranes.

Pregnancy: It is not known whether **AKTIPAK™** can cause fetal harm when administered to a pregnant woman. **AKTIPAK™** should be given to a pregnant woman only if clearly needed. It is not known whether the ingredients of **AKTIPAK™** are excreted in human milk. Therefore, caution should be exercised when erythromycin is administered to a nursing woman.

Pediatric Use: The safety and effectiveness of **AKTIPAK™** in pediatric patients below 12 years of age have not been established.

Adverse Reactions: The most frequently reported adverse events reported in clinical trials include: dry skin, application site reaction, blepharitis, pruritus, and photosensitivity.

Please see the Brief Summary of Full Prescribing Information on the next page. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit http://www.fda.gov/Safety/MedWatch/default.htm or call 1-800-FDA-1088.

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References: 1. Aktipak™ (erythromycin and benzoyl peroxide) Gel, 3%/5% [package insert]. Wayne, PA: Cutanea Life Sciences, Inc.; 2017. **2.** Data on file, Cutanea Life Sciences, Inc. 2017.

Aktipak™
(erythromycin and benzoyl peroxide) Gel, 3%/5%

BRIEF SUMMARY OF PRESCRIBING INFORMATION

This Brief Summary does not include all the information needed to use AKTIPAK™ safely and effectively. See full prescribing information for AKTIPAK™.

AKTIPAK™ (erythromycin and benzoyl peroxide) Gel, 3%/5% - For Dermatological Use Only – Not for Ophthalmic Use

INDICATIONS AND USAGE
Aktipak™ is indicated for the topical treatment of acne vulgaris.

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General: For topical use only; not for ophthalmic use. Concomitant topical acne therapy should be used with caution because a possible cumulative irritancy effect may occur, especially with the use of peeling, desquamating or abrasive agents. If severe irritation develops, discontinue use and institute appropriate therapy. The use of antibiotic agents may be associated with the overgrowth of nonsusceptible organisms. If this occurs, discontinue use and take appropriate measures. Avoid contact with eyes and all mucous membranes.

Information for Patients: Patients using Aktipak™ should receive the following information and instructions:

1. Patients should be informed that they will need to mix this medication prior to use. The medication will be dispensed in one foil pouch which contains medication in two separated compartments.
2. The contents must be mixed thoroughly by the patient (in the palm of the hand), prior to application.
3. Patients should apply the product immediately after mixing, then the hands should be washed.
4. Do not mix or apply near an open flame.
5. Aktipak™ may bleach hair or colored fabric.
6. Excessive or prolonged exposure to sunlight should be limited. To minimize exposure to sunlight, a hat or other clothing should be worn.
7. This medication is to be used as directed by a physician. It is for external use only. Avoid contact with the eyes, mouth, and all mucous membranes as this product may be irritating.
8. Patients should report to their physician any signs of local adverse reactions.
9. This medication should not be used for any disorder other than that for which it was prescribed.
10. Patients should not use any other topical acne preparation unless otherwise directed by physician.
11. Patients should be instructed to review the instructions for use on the product carton.
12. This medication should be stored at room temperature away from heat and any open flame.

Carcinogenesis, Mutagenesis, Impairment of Fertility:
The combination of benzoyl peroxide and erythromycin in Aktipak™ has not been evaluated for its carcinogenic or mutagenic potential or for its effects on fertility.

Benzoyl peroxide has been shown to be a tumor promoter and progression agent in a number of animal studies. The clinical significance of this is unknown.

Benzoyl peroxide in acetone at doses of 5 and 10 mg administered twice per week induced skin tumors in transgenic Tg.AC mice in a study using 20 weeks of topical treatment.

Benzoyl peroxide has been found to cause DNA strand breaks in a variety of mammalian cell types, to be mutagenic in *Salmonella typhimurium* tests by some but not all investigators, and to cause sister chromatid exchanges in Chinese hamster ovary cells.

No animal studies have been performed to evaluate the carcinogenic potential or effects on fertility of topical erythromycin. However, long-term (2-year) oral studies in rats with erythromycin base and erythromycin ethylsuccinate and in rats and mice with erythromycin stearate did not provide evidence of tumorigenicity.

The genotoxicity of erythromycin stearate has been evaluated in the *Salmonella typhimurium* reverse mutation assay, the mouse L5178Y lymphoma cell assay, and for sister chromatid exchanges and chromosomal aberrations in CHO cells. These studies indicated that erythromycin stearate was not genotoxic. There was no apparent effect on male or female fertility in rats fed erythromycin base at levels up to 0.25% of diet.

Pregnancy: Teratogenic Effects: Pregnancy CATEGORY C: Animal reproduction studies have not been conducted with Aktipak™ or benzoyl peroxide.

There was no evidence of teratogenicity or any other adverse effect on reproduction in female rats fed erythromycin base (up to 0.25% diet) prior to and during mating, during gestation and through weaning of two successive litters.

There are no well-controlled trials in pregnant women with Aktipak™. It is also not known whether Aktipak™ can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Aktipak™ should be given to a pregnant woman only if clearly needed.

Nursing Women: It is not known whether the ingredients of Aktipak™ are excreted in human milk after topical application. However, erythromycin is excreted in human milk following oral and parenteral erythromycin administration. Therefore, caution should be exercised when erythromycin is administered to a nursing woman.

Pediatric Use: Safety and effectiveness of this product in pediatric patients below 12 years of age have not been established.

ADVERSE REACTIONS
During clinical trials, 550 acne patients were studied. Of these patients, 236 were treated with Aktipak™. The most frequently reported adverse event considered at least possibly related was dry skin (7.6%) as compared to Vehicle (3.9%). Application site reactions (stinging, burning sensation, tingling, erythema) were reported in 2.5% of patients versus 1.3% of Vehicle patients. Blepharitis, pruritus and photosensitivity reactions were reported in <2% of patients who used the dual pouch product.

Treatment Groups Summaries
Number of Patients (%)

COSTART Term	Aktipak™ N = 236	Aktipak™ Vehicle N = 153	Benzamycin Topical Gel N = 121	Benzamycin Topical Gel Vehicle N = 40
DRY SKIN	18 (7.6%)	6 (3.9%)	6 (5.0%)	0
APPLICATION SITE REACTION (stinging, erythema, and burning)	6 (2.5%)	2 (1.3%)	1 (0.8%)	0
BLEPHARITIS	4 (1.7%)	1 (0.7%)	0	1 (2.5%)
PRURITUS	4 (1.7%)	2 (1.3%)	3 (2.5%)	0
PHOTO-SENSITIVITY REACTION (Sunburn, stinging with sun exposure)	3 (1.3%)	0	0	0
PEELING	1 (0.5%)	1 (0.7%)	0	0

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Dermoscopy and Reflectance Confocal Microscopy in Pedunculated Basal Cell Carcinoma

By Seda Yildiz, MD, Isil Karaarslan, MD, Banu Yaman, MD and Fezal Ozdemir, MDPA-C

There have been limited cases of pedunculated basal cell carcinoma (BCC) reported in the literature. The dermoscopic features were described in only one of them. However, not one of them described the confocal microscopy features. In this report we presented a case of pedunculated basal cell carcinoma (BCC) with dermoscopic and reflectance confocal microscopy features.

INTRODUCTION

Pedunculated basal cell carcinoma (BCC) is a rare BCC variant. There have been limited cases reported in the PubMed database.[1-6] Dermoscopic features were reported in only one of them and not one described reflectance confocal microscopy (RCM) features.[6]

CASE

A 7×5mm slight brown-gray pigmented pedunculated lesion was detected on the right post-auricular region on the routine skin examination of a 60-year-old woman. She had a history of multiple BCCs due to radiotherapy for the treatment of lymphoma in childhood. The lesion displayed arborizing vessels, multiple blue-gray globules and ovoid nests on dermoscopy *(see Figure 1)*.

On RCM, at the epidermal layer, polarization (streaming) and some dendritic cells and at the dermoepidermal junctional level, and multiple tumor islands with different sizes were observed. In addition, there were many canalicular vessels all throughout the lesion (Vivascope 3000 Handheld, Mavig GmbH, Munich, Germany). A pedunculated nodular BCC was diagnosed with the large basaloid tumor islands with peripheral palisading and retraction artifact and dilated vascular spaces on histopathology *(see Figure 2)*.

The differential diagnosis of pigmented pedunculated lesion may sometimes be challenging and include an acrochordon, seborrheic keratosis, condyloma, dermal nevus, BCC, eccrine poroma or trichoblastoma. Moreover, a pedunculated melanoma should also be excluded. Thus, in vivo diagnostic techniques such as dermoscopy and RCM may play a crucial role in the differential diagnosis.

CONCLUSION

There have been rare cases of pedunculated BCC reported in the literature. Dermoscopic features were mentioned in only one report describing multiple acrochordon-like BCCs in a patient with Gorlin-Goltz

Figure 1: *(A, B) Slight brown-gray pigmented pedunculated lesion. (C, D) Arborizing vessels, multiple blue-gray globules and ovoid nests on dermoscopy.*

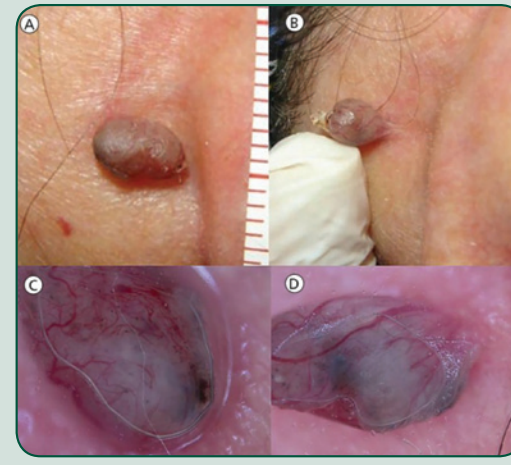
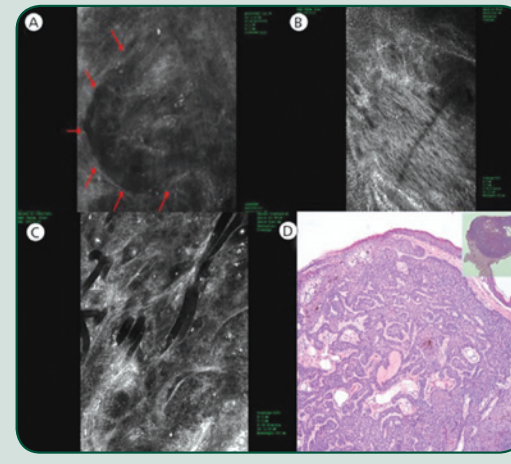


Figure 2: *(A) Bright tumor island (red arrows). (B) Epidermal polarization. (C) Tumor island and canalicular vessels. (D) Atrophic epidermis, large basaloid tumor islands and melanophages (H&Ex40) (Inset: Pedunculated nodular BCC [H&Ex20]).*



syndrome.[6] In that case, the dermoscopic features observed were multiple or isolated gray-blue globules and/or telangiectases of different caliber and number of branches. Other dermoscopic features of BCC, such as ulceration, maple leaf-like areas, or spoke-wheel areas, were not detected. The dermoscopic features observed in the present case were similar to those findings. On the other hand, RCM findings were not described in any of the cases in the literature. In the present case, observing the typical RCM criteria for BCC helped in making a more confident preoperative diagnosis. To our knowledge, this is the first RCM description of a pedunculated BCC.

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Seda Yildiz, MD works at the Department of Dermatology, Faculty of Medicine, University of Ege, Izmir, Turkey. Isil Karaarslan, MD works at the Department of Dermatology, Faculty of Medicine, University of Ege, Izmir, Turkey. Banu Yaman, MD works at the Department of Pathology, Faculty of Medicine, University of Ege, Izmir, Turkey. Fezal Ozdemir, MD works at the Department of Dermatology, Faculty of Medicine, University of Ege, Izmir, Turkey. All authors have indicated no conflicts of interest to disclose relating to the content of this article.

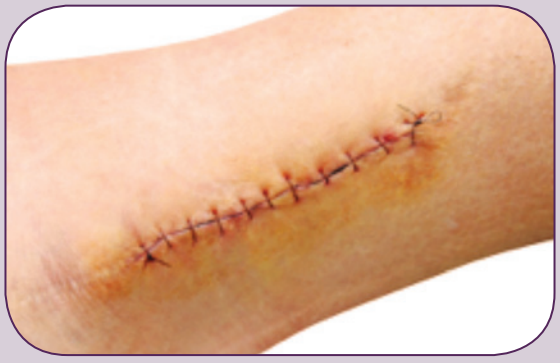
SURGICAL wisdom

Dermcast.tv Blog -

Dog Ears After Mohs: Fix Now Or Wait Till Later?

By Martha L. Sikes, MS, RPh, PA-C

The puckering of skin that occurs after the closure of the wound after Mohs micrographic surgery (MMS) are commonly known as "dog-ears." They are a result of the fact that most MMS wounds are circular, oval, or asymmetrical in shape, making a neater closure more challenging. Since these are not a desirable result, many workarounds and interventional techniques have been developed to correct these defects. One choice is to forego any intervention in the hopes they will settle out after swelling resolves and wound contraction takes place.



A recent study looked at regression of dog-ears after surgery and attempts to provide guidance on whether certain dog-ears may require other interventions to correct certain dog-ears at the time of surgery. A total of 77 patients were enrolled accounting for 140 dog-ears. Patients were advised that these defects would occur and offered the option for surgical correction at any time. Wounds were located on either the head and neck, hand, extremity, or trunk. At 6 months following MMS, patients were examined to observe the site and assess for resolution of the dog-ear.

The results showed that the vast majority (81%) completely resolved after 6 months. As for their location on the body, 97% of the dog-ears on the hands resolved, no matter the original height of the defect, 94% on the trunk, 78% on the limbs, and 67% on the head or neck.

The authors conclude that since attempting to resolve dog-ears at the time of surgery can result in larger wounds and scars, when patients have MMS on hands, trunk or limbs, the dog-ears should be left to resolve on their own. However, dog-ears in cosmetically sensitive areas, such as the head and neck, should continue to be corrected at the time of surgery.

Dermcast.tv Blog Post: October 9, 2017
Source: NCBI
Adapted from the original article.

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TOP 9 REASONS

Dermatology PAs

[or those PAs interested in dermatology]

Should Become a Member of the SDPA

The largest of 26 specialty organizations under the American Academy of Physician Assistants (AAPA), the Society of Dermatology Physician Assistants (SDPA) is a non-profit professional association focused on empowering, educating and advancing PAs currently working in the field of dermatology and those who would like to work in the field.

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Dermatology EBM

Does aloe vera gel increase the efficacy of tretinoin cream in the treatment of mild to moderate acne vulgaris?

By Chelsea Lettieri, MMS, PA-C

A 19 year-old female presents to your rural dermatology office with moderate acne vulgaris. She is frustrated because she has tried in the past topical benzoyl peroxide/clindamycin gel, adapalene gel, tretinoin gel, and oral antibiotics without any significant reduction in her acne. She also states that the topical treatments caused erythema, peeling, and burning. The patient has no other significant past medical history. Upon inspection, the patient is found to have over twenty open and closed comedones and over fifteen papules and pustules distributed on her face.

You consider adding an anti-inflammatory topical, such as aloe vera gel to help reduce irritation from topical tretinoin, but you are unsure if research supports its use. You also question its efficacy and exactly how it should be used in this instance.

CLINICAL QUESTION

The clinical question to be answered is whether aloe vera gel combined with tretinoin cream is more effective than tretinoin cream alone in the treatment of mild to moderate acne vulgaris?

SEARCH CRITERIA AND RESULTS

This clinical question falls under the category of therapy. Randomized clinical trials are the most appropriate type of study for answering a therapy question.

A search of medical literature was conducted through PubMed using the keywords *acne vulgaris, tretinoin, efficacy,* and *aloe*. Acne vulgaris yielded 10,849 results. Combining *acne vulgaris* and *tretinoin* yielded 789 results. The combination of *acne vulgaris, tretinoin,* and *efficacy* yielded 167 results. The search was then limited to only clinical trials involving humans that were published in the last 5 years, which yielded 15 articles. Adding the keyword *aloe* limited the result to 1 article. Further searches of PubMed, evidence-based medicine databases, and online search engines did not yield additional pertinent articles that were of a higher level of evidence. Hajheydari et al. was therefore chosen because it contained a randomized, double-blind, prospective trial involving patients with mild to moderate acne vulgaris and answered the clinical question with a high level of evidence.[1]

EVALUATING THE EVIDENCE

Hajheydari et al. conducted a randomized, double-blind, prospective trial involving 75 patients, 11 years and older, with mild to moderate acne who were not satisfied with their previous acne treatments. Thirty-seven patients in the case group applied 50% aloe vera gel in the morning and evening and 38 patients in the control group applied placebo gel in the morning and evening for 8 weeks. The patients in both groups also applied tretinoin 0.025% cream in the evening. Both groups washed their faces with non-medicated soap in the morning and evening before applying the topical medications. In the evening, the second medication in both groups was applied 10 to 15 minutes after the first medication. Before starting the medications, each patient's acne was given a score based on the global acne grading system (GAGS) scale. The number of acne lesions, both inflammatory and comedones, were counted at baseline, 2 weeks, 4 weeks, and 8 weeks. The percent of reduction of acne lesions from baseline based on the GAGS scale was also calculated. The adverse effects (scaling, edema, erythema, burning, and itching) were rated on a scale from 0 (none) to 3 (severe). For the final determination of efficacy, the total lesion count (TLC) and acne severity index (ASI) were calculated based on the following formulas:

- TLC = comedones + papules + pustules
- ASI = papules + (2 x pustules) + (comedones/4)

The primary outcome measure was a decrease in TLC, ASI, and adverse effects after 8 weeks with the use of aloe vera gel combined with tretinoin cream. TLC was significantly reduced in the case group after 8 weeks (p=0.0015).[1] There was also a significant decrease in ASI after 8 weeks in the case group (p=0.0010).[1] After 8 weeks, 78.7% of patients who used aloe vera gel with tretinoin cream had clear skin according to the GAGS scale as compared to only 23.3% of patients in the control group.[1] The combination therapy was effective in reducing both inflammatory and non-inflammatory lesions. There was no significant difference between the severity of scaling, edema, burning, and itching after 8 weeks between the case group and the control group. However, there was a significant difference seen in erythema. After week 8, only 3.3% of the case group reported erythema as compared to 20% of the control group.[1] The erythema was also reported as less severe in the case group than in the control group.

The major limitations of this study were the small sample size (75 patients) and the loss to follow-up (20%). Sixty of the 75 patients, 30 in each group, were included in the efficacy analysis.[1] Three patients in the control group suffered from a severe allergic reaction and 12 male patients discontinued treatment due to personal reasons. As a result of the loss to follow-up, only female patients completed the study and were included in the analysis. Further studies should be done with a larger sample size and both females and males in order to better assess the efficacy. A larger sample size will also increase the likelihood of male patients completing the study.

CLINICAL BOTTOM LINE

Aloe vera gel in combination with tretinoin cream was found to be more effective at treating mild to moderate acne vulgaris than tretinoin cream and placebo. The combination also resulted in less erythema. PAs treating patients with mild to moderate acne vulgaris should consider the use of aloe vera gel in combination with tretinoin cream, especially in patients who have not had success with previous acne treatments or have had significant adverse effects from topical tretinoin. However, PAs should follow any ongoing research that may emerge relating to the use of aloe vera gel with topical tretinoin in the treatment of acne vulgaris.

REFERENCES

1. Hajheydari Z, Saeedi M, Morteza-Semnani K, Soltani A. Effect of Aloe vera topical gel combined with tretinoin in treatment of mild and moderate acne vulgaris: a randomized, double-blind, prospective trial. J Dermatolog Treat. 2014;25(2):123-129. doi:10.3109/09546634.2013.768328.

Chelsea Lettieri, MMS, PA-C is a graduate of Salus University's Physician Assistant Program. She has indicated no relationships to disclose relating to the content of this article.

Ortho | Dermatologics

FOR MODERATE TO SEVERE INFLAMMATORY ACNE

SOLODYN®
(MINOCYCLINE HCl, USP) EXTENDED RELEASE TABLETS

MATCH THE POWER TO THE PATIENT[1]

THREE CUSTOMIZED, WEIGHT-BASED STRENGTHS

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Indication and Usage

SOLODYN® is indicated to treat only inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age and older.

SOLODYN did not demonstrate any effect on non-inflammatory acne lesions. Safety of SOLODYN has not been established beyond 12 weeks of use. This formulation of minocycline has not been evaluated in the treatment of infections. To reduce the development of drug-resistant bacteria as well as to maintain the effectiveness of other antibacterial drugs, SOLODYN should be used only as indicated.

Important Safety Information for SOLODYN Tablets

- This drug is contraindicated in persons who have shown hypersensitivity to any of the tetracyclines
- MINOCYCLINE, LIKE OTHER TETRACYCLINE-CLASS DRUGS, CAN CAUSE FETAL HARM WHEN ADMINISTERED TO A PREGNANT WOMAN. Should not be used during pregnancy or by individuals of either gender who are attempting to conceive a child; concurrent use of tetracyclines with oral contraceptives may render oral contraceptives less effective.
- TETRACYCLINE DRUGS SHOULD NOT BE USED DURING TOOTH DEVELOPMENT (LAST HALF OF PREGNANCY AND UP TO 8 YEARS OF AGE) AS THEY MAY CAUSE PERMANENT DISCOLORATION OF TEETH.
- Pseudomembranous colitis has been reported with nearly all antibacterial agents and may range from mild to life-threatening; therefore, it is important to consider this diagnosis in patients who present with diarrhea subsequent to the administration of antibacterial agents
- Dose adjustments may be necessary in patients with renal impairment to avoid liver toxicity
- Central nervous system side effects, including light-headedness, dizziness, and vertigo, have been reported with minocycline therapy
- Pseudotumor cerebri (benign intracranial hypertension) and autoimmune syndromes have been associated with the use of tetracyclines
- Cases of anaphylaxis, serious skin reactions, erythema multiforme, and drug rash with eosinophilia and systemic symptoms have been reported postmarketing with minocycline use. Discontinue SOLODYN immediately if symptoms occur. In rare cases, photosensitivity has been reported.
- The most commonly observed adverse reactions are headache, fatigue, dizziness, and pruritus

To report SUSPECTED ADVERSE REACTIONS contact Ortho Dermatologics at 1-800-321-4576 or FDA at 1-800-FDA-1088 or visit www.fda.gov/medwatch.

Please see Brief Summary of Prescribing Information on the following pages.

Reference: 1. SOLODYN Tablets Package Insert. Valeant Pharmaceuticals North America LLC.

SOLODYN® (MINOCYCLINE HCl, USP) EXTENDED RELEASE TABLETS

SUMMARY OF PRESCRIBING INFORMATION

This Brief Summary does not include all the information needed to use SOLODYN safely and effectively.

See full Prescribing Information.

SOLODYN®

(minocycline HCl, USP) Extended Release Tablets

Rx Only

KEEP OUT OF REACH OF CHILDREN

INDICATIONS AND USAGE

Indication

SOLODYN is indicated to treat only inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age and older.

Limitations of Use

SOLODYN did not demonstrate any effect on non-inflammatory acne lesions. Safety of SOLODYN has not been established beyond 12 weeks of use. This formulation of minocycline has not been evaluated in the treatment of infections. To reduce the development of drug resistant bacteria as well as to maintain the effectiveness of other antibacterial drugs, SOLODYN should be used only as indicated *(see Warnings and Precautions)*.

CONTRAINDICATIONS

This drug is contraindicated in persons who have shown hypersensitivity to any of the tetracyclines.

Warnings and Precautions

Teratogenic Effects

A. MINOCYCLINE, LIKE OTHER TETRACYCLINE-CLASS DRUGS, CAN CAUSE FETAL HARM WHEN ADMINISTERED TO A PREGNANT WOMAN. IF ANY TETRACYCLINE IS USED DURING PREGNANCY OR IF THE PATIENT BECOMES PREGNANT WHILE TAKING THESE DRUGS, THE PATIENT SHOULD BE APPRISED OF THE POTENTIAL HAZARD TO THE FETUS.

SOLODYN should not be used during pregnancy or by individuals of either gender who are attempting to conceive a child *(see Use in Specific Populations & Nonclinical Toxicology)*.

B. THE USE OF DRUGS OF THE TETRACYCLINE CLASS DURING TOOTH DEVELOPMENT (LAST HALF OF PREGNANCY, INFANCY, AND CHILDHOOD UP TO THE AGE OF 8 YEARS) MAY CAUSE PERMANENT DISCOLORATION OF THE TEETH (YELLOW-GRAY-BROWN).

This adverse reaction is more common during long-term use of the drug but has been observed following repeated short-term courses. Enamel hypoplasia has also been reported. TETRACYCLINE DRUGS, THEREFORE, SHOULD NOT BE USED DURING TOOTH DEVELOPMENT.

C. All tetracyclines form a stable calcium complex in any bone-forming tissue. A decrease in fibula growth rate has been observed in premature human infants given oral tetracycline in doses of 25 mg/kg every 6 hours. This reaction was shown to be reversible when the drug was discontinued.

Results of animal studies indicate that tetracyclines cross the placenta, are found in fetal tissues, and can cause retardation of skeletal development on the developing fetus. Evidence of embryotoxicity has been noted in animals treated early in pregnancy *(see Use in Specific Populations)*.

Pseudomembranous Colitis

Clostridium difficile associated diarrhea (CDAD) has been reported with nearly all antibacterial agents, including minocycline, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of *C. difficile*.

C. difficile produces toxins A and B which contribute to the development of CDAD. Hypertoxin producing strains of *C. difficile* cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibiotic use. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents.

If CDAD is suspected or confirmed, ongoing antibiotic use not directed against *C. difficile* may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of *C. difficile*, and surgical evaluation should be instituted as clinically indicated.

Hepatotoxicity

Post-marketing cases of serious liver injury, including irreversible drug-induced hepatitis and fulminant hepatic failure (sometimes fatal) have been reported with minocycline use in the treatment of acne.

Metabolic Effects

The anti-anabolic action of the tetracyclines may cause an increase in BUN. While this is not a problem in those with normal renal function, in patients with significantly impaired function, higher serum levels of tetracycline-class drugs may lead to azotemia, hyperphosphatemia, and acidosis. If renal impairment exists, even usual oral or parenteral doses may lead to excessive systemic accumulations of the drug and possible liver toxicity. Under such conditions, lower than usual total doses are indicated, and if therapy is prolonged, serum level determinations of the drug may be advisable.

Central Nervous System Effects

Central nervous system side effects including light-headedness, dizziness or vertigo have been reported with minocycline therapy. Patients who experience these symptoms should be cautioned about driving vehicles or using hazardous machinery while on minocycline therapy. These symptoms may disappear during therapy and usually rapidly disappear when the drug is discontinued.

Benign Intracranial Hypertension

Pseudotumor cerebri (benign intracranial hypertension) in adults and adolescents has been associated with the use of tetracyclines. Minocycline has been reported to cause or precipitate pseudotumor cerebri, the hallmark of which is papilledema. Clinical manifestations include headache and blurred vision. Bulging fontanels have been associated with the use of tetracyclines in infants. Although signs and symptoms of pseudotumor cerebri resolve after discontinuation of treatment, the possibility for permanent sequelae such as visual loss that may be permanent or severe exists. Patients should be questioned for visual disturbances prior to initiation of treatment with tetracyclines. If visual disturbance occurs during treatment, patients should be checked for papilledema. Concomitant use of isotretinoin and minocycline should be avoided because isotretinoin, a systemic retinoid, is also known to cause pseudotumor cerebri.

Autoimmune Syndromes

Tetracyclines have been associated with the development of autoimmune syndromes. The long-term use of minocycline in the treatment of acne has been associated with drug-induced lupus-like syndrome, autoimmune hepatitis and vasculitis. Sporadic cases of serum sickness have presented shortly after minocycline use. Symptoms may be manifested by fever, rash, arthralgia, and malaise. In symptomatic patients, liver function tests, ANA, CBC, and other appropriate tests should be performed to evaluate the patients. Use of all tetracycline-class drugs should be discontinued immediately.

Photosensitivity

Photosensitivity manifested by an exaggerated sunburn reaction has been observed in some individuals taking tetracyclines. This has been reported rarely with minocycline. Patients should minimize or avoid exposure to natural or artificial sunlight (tanning beds or UVA/B treatment) while using minocycline. If patients need to be outdoors while using minocycline, they should wear loose-fitting clothes that protect skin from sun exposure and discuss other sun protection measures with their physician.

Serious Skin/Hypersensitivity Reaction

Cases of anaphylaxis, serious skin reactions (e.g. Stevens Johnson syndrome), erythema multiforme, and drug rash with eosinophilia and systemic symptoms (DRESS) syndrome have been reported postmarketing with minocycline use in patients with acne. DRESS syndrome consists of cutaneous reaction (such as rash or exfoliative dermatitis), eosinophilia, and one or more of the following visceral complications such as: hepatitis, pneumonitis, nephritis, myocarditis, and pericarditis. Fever and lymphadenopathy may be present. In some cases, death has been reported. If this syndrome is recognized, the drug should be discontinued immediately.

Tissue Hyperpigmentation

Tetracycline-class antibiotics are known to cause hyperpigmentation. Tetracycline therapy may induce hyperpigmentation in many organs, including nails, bone, skin, eyes, thyroid, visceral tissue, oral cavity (teeth, mucosa, alveolar bone), sclerae and heart valves. Skin and oral pigmentation has been reported to occur independently of time or amount of drug administration, whereas other tissue pigmentation has been reported to occur upon prolonged administration. Skin pigmentation includes diffuse pigmentation as well as over sites of scars or injury.

Development of Drug Resistant Bacteria

Bacterial resistance to the tetracyclines may develop in patients using SOLODYN, therefore, the susceptibility of bacteria associated with infection should be considered in selecting antimicrobial therapy. Because of the potential for drug-resistant bacteria to develop during the use of SOLODYN, it should be used only as indicated.

Superinfection

As with other antibiotic preparations, use of SOLODYN may result in overgrowth of nonsusceptible organisms, including fungi. If superinfection occurs, SOLODYN should be discontinued and appropriate therapy instituted.

Laboratory Monitoring

Periodic laboratory evaluations of organ systems, including hematopoietic, renal and hepatic studies should be performed. Appropriate tests for autoimmune syndromes should be performed as indicated.

ADVERSE REACTIONS

Clinical Trial Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials cannot be directly compared to rates in the clinical trials of another drug, and may not reflect the rates observed in practice.

The following table summarizes selected adverse reactions reported in clinical trials at a rate of ≥1% for SOLODYN.

Selected Treatment-Emergent Adverse Reactions in at least 1% of Clinical Trial Subjects

Adverse Reactions	SOLODYN (1 mg/kg) N=674 (%)	PLACEBO N=364 (%)
At least one treatment-emergent event	379 (56)	197 (54)
Headache	152 (23)	83 (23)
Fatigue	62 (9)	24 (7)
Dizziness	59 (9)	17 (5)
Pruritus	31 (5)	16 (4)
Malaise	26 (4)	9 (3)
Mood alteration	17 (3)	9 (3)
Somnolence	13 (2)	3 (1)
Urticaria	10 (2)	1 (0)
Tinnitus	10 (2)	5 (1)
Arthralgia	9 (1)	2 (0)
Vertigo	8 (1)	3 (1)
Dry mouth	7 (1)	5 (1)
Myalgia	7 (1)	4 (1)

Postmarketing Experience

Adverse reactions that have been reported with minocycline hydrochloride use in a variety of indications include:

Skin and hypersensitivity reactions: fixed drug eruptions, balanitis, erythema multiforme, Stevens-Johnson syndrome, anaphylactoid purpura, photosensitivity, pigmentation of skin and mucous membranes, hypersensitivity reactions, angioneurotic edema, anaphylaxis, DRESS syndrome *(see Warnings and Precautions)*.

Autoimmune conditions: polyarthralgia, pericarditis, exacerbation of systemic lupus, pulmonary infiltrates with eosinophilia, transient lupus-like syndrome.

Central nervous system: pseudotumor cerebri, bulging fontanels in infants, decreased hearing.

Endocrine: brown-black microscopic thyroid discoloration, abnormal thyroid function.

Oncology: thyroid cancer.

Oral: glossitis, dysphagia, tooth discoloration.

Gastrointestinal: enterocolitis, pancreatitis, hepatitis, liver failure.

Renal: reversible acute renal failure.

Hematology: hemolytic anemia, thrombocytopenia, eosinophilia. Preliminary studies suggest that use of minocycline may have deleterious effects on human spermatogenesis

(see Nonclinical Toxicology).

DRUG INTERACTIONS

Anticoagulants

Because tetracyclines have been shown to depress plasma prothrombin activity, patients who are on anticoagulant therapy may require downward adjustment of their anticoagulant dosage.

Penicillin

Since bacteriostatic drugs may interfere with the bactericidal action of penicillin, it is advisable to avoid giving tetracycline-class drugs in conjunction with penicillin.

Methoxyflurane

The concurrent use of tetracycline and methoxyflurane has been reported to result in fatal renal toxicity.

Antacids and Iron Preparations

Absorption of tetracyclines is impaired by antacids containing aluminum, calcium or magnesium and iron-containing preparations.

Low Dose Oral Contraceptives

In a multi-center study to evaluate the effect of SOLODYN on low dose oral contraceptives, hormone levels over one menstrual cycle with and without SOLODYN 1 mg/kg once-daily were measured. Based on the results of this trial, minocycline-related changes in estradiol, progestinic hormone, FSH and LH plasma levels, of breakthrough bleeding, or of contraceptive failure, cannot be ruled out. To avoid contraceptive failure, female patients are advised to use a second form of contraceptive during treatment with minocycline.

Drug/Laboratory Test Interactions

False elevations of urinary catecholamine levels may occur due to interference with the fluorescence test.

USE IN SPECIFIC POPULATIONS

Pregnancy

Teratogenic Effects: Pregnancy category D (see Warnings and Precautions)

SOLODYN should not be used during pregnancy. If the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus and stop treatment immediately.

There are no adequate and well-controlled studies on the use of minocycline in pregnant women. Minocycline, like other tetracycline-class drugs, crosses the placenta and may cause fetal harm when administered to a pregnant woman.

Rare spontaneous reports of congenital anomalies including limb reduction have been reported with minocycline use in pregnancy in post-marketing experience. Only limited information is available regarding these reports; therefore, no conclusion on causal association can be established.

Minocycline induced skeletal malformations (bent limb bones) in fetuses when administered to pregnant rats and rabbits in doses of 30 mg/kg/day and 100 mg/kg/day, respectively, (resulting in approximately 3 times and 2 times, respectively, the systemic exposure to minocycline observed in patients as a result of use of SOLODYN). Reduced mean fetal body weight was observed in studies in which minocycline was administered to pregnant rats at a dose of 10 mg/kg/day (which resulted in approximately the same level of systemic exposure to minocycline as that observed in patients who use SOLODYN).

Minocycline was assessed for effects on peri- and post-natal development of rats in a study that involved oral administration to pregnant rats from day 6 of gestation through the period of lactation (postpartum day 20), at dosages of 5, 10, or 50 mg/kg/day. In this study, body weight gain was significantly reduced in pregnant females that received 50 mg/kg/day (resulting in approximately 2.5 times the systemic exposure to minocycline observed in patients as a result of use of SOLODYN). No effects of treatment on the duration of the gestation period or the number of live pups born per litter were observed. Gross external anomalies observed in F1 pups (offspring of animals that received minocycline) included reduced body size, improperly rotated forelimbs, and reduced size of extremities. No effects were observed on the physical development, behavior, learning ability, or reproduction of F1 pups, and there was no effect on gross appearance of F2 pups (offspring of F1 animals).

Nursing Mothers

Tetracycline-class antibiotics are excreted in human milk. Because of the potential for serious adverse effects on bone and tooth development in nursing infants from the tetracycline-class antibiotics, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother *(see Warnings and Precautions)*.

Pediatric Use

SOLODYN is indicated to treat only inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years and older. Safety and effectiveness in pediatric patients below the age of 12 has not been established.

Use of tetracycline-class antibiotics below the age of 8 is not recommended due to the potential for tooth discoloration *(see Warnings and Precautions)*.

Geriatric Use

Clinical studies of SOLODYN did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and concomitant disease or other drug therapy.

OVERDOSAGE

In case of overdosage, discontinue medication, treat symptomatically and institute supportive measures. Minocycline is not removed in significant quantities by hemodialysis or peritoneal dialysis.

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis—In a carcinogenicity study in which minocycline HCl was orally administered to male and female rats once daily for up to 104 weeks at dosages up to 200 mg/kg/day, minocycline HCl was associated in both genders with follicular cell tumors of the thyroid gland, including increased incidences of adenomas, carcinomas and the combined incidence of adenomas and carcinomas in males, and adenomas and the combined incidence of adenomas and carcinomas in females. In a carcinogenicity study in which minocycline HCl was orally administered to male and female mice once daily for up to 104 weeks at dosages up to 150 mg/kg/day, exposure to minocycline HCl did not result in a significantly increased incidence of neoplasms in either males or females.

Mutagenesis—Minocycline was not mutagenic *in vitro* in a bacterial reverse mutation assay (Ames test) or CHO/HGPRT mammalian cell assay in the presence or absence of metabolic activation. Minocycline was not clastogenic *in vitro* using human peripheral blood lymphocytes or *in vivo* in a mouse micronucleus test.

Impairment of Fertility—Male and female reproductive performance in rats was unaffected by oral doses of minocycline of up to 300 mg/kg/day (which resulted in up to approximately 40 times the level of systemic exposure to minocycline observed in patients as a result of use of SOLODYN). However, oral administration of 100 or 300 mg/kg/day of minocycline to male rats (resulting in approximately 15 to 40 times the level of systemic exposure to minocycline observed in patients as a result of use of SOLODYN) adversely affected spermatogenesis. Effects observed at 300 mg/kg/day included a reduced number of sperm cells per gram of epididymis, an apparent reduction in the percentage of sperm that were motile, and (at 100 and 300 mg/kg/day) increased numbers of morphologically abnormal sperm cells. Morphological abnormalities observed in sperm samples included absent heads, misshapen heads, and abnormal flagella.

Limited human studies suggest that minocycline may have a deleterious effect on spermatogenesis.

SOLODYN should not be used by individuals of either gender who are attempting to conceive a child.

HOW SUPPLIED/STORAGE AND HANDLING

How Supplied

SOLODYN (minocycline HCl, USP) Extended Release Tablets are supplied as aqueous film coated tablets containing minocycline hydrochloride equivalent to 55 mg, 65 mg, 80 mg, 105 mg or 115 mg minocycline, are supplied as follows.

The 55 mg extended release tablets are pink, unscored, coated, and debossed with "DYN-055" on one side. Each tablet contains minocycline hydrochloride equivalent to 55 mg minocycline, supplied as follows:

NDC 99207-465-30 Bottle of 30

The 65 mg extended release tablets are blue, unscored, coated, and debossed with "DYN-065" on one side. Each tablet contains minocycline hydrochloride equivalent to 65 mg minocycline, supplied as follows:

NDC 99207-463-30 Bottle of 30

The 80 mg extended release tablets are dark gray, unscored, coated, and debossed with "DYN-080" on one side. Each tablet contains minocycline hydrochloride equivalent to 80 mg minocycline, supplied as follows:

NDC 99207-466-30 Bottle of 30

The 105 mg extended release tablets are purple, unscored, coated, and debossed with "DYN-105" on one side. Each tablet contains minocycline hydrochloride equivalent to 105 mg minocycline, supplied as follows:

NDC 99207-467-30 Bottle of 30

The 115 mg extended release tablets are green, unscored, coated, and debossed with "DYN-115" on one side. Each tablet contains minocycline hydrochloride equivalent to 115 mg minocycline, supplied as follows:

NDC 99207-464-30 Bottle of 30

Storage

Store at 25ºC (77ºF); excursions are permitted to 15º-30ºC (59º-86ºF) [See USP Controlled Room Temperature].

Handling

Keep out of reach of children

Protect from light, moisture, and excessive heat.

Dispense in tight, light-resistant container with child-resistant closure.

PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information).

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COSMETIC pearls

Dermcast.tv Blog

Does Topical Fluorouracil Improve Effects of Photoaging?

By Martha L. Sikes, MS, RPh, PA-C

Many patients are concerned about the cosmetic effects of photoaging, premature skin aging attributable to long-term UV radiation exposure. Typically, patients present with lentigines, rhytides, telangiectasias, inelasticity, and hyperpigmentation. There are numerous treatments that reduce the effects of photoaging, such as over-the-counter topicals, topical retinoids, chemical peels, and laser therapy. A recent study looked at topical fluorouracil, 5%, to evaluate its effectiveness in reversing photoaging.

Systemic fluorouracil has been shown to lead to improvements in skin texture and wrinkling, but the effects due to topical applications have not been well documented. Using a secondary analysis from a study of primarily elderly men with severe sun damage, authors sought to investigate changes in photodamage after a standard course of topical fluorouracil, 5%, cream. Participants were randomized to two groups: one group using topical fluorouracil, 5%, cream, the other a vehicle control cream. The creams were applied to the face and ears twice daily for 4 weeks. Authors used four validated photonumeric scales to capture changes at various points from baseline through 18 months after treatment.

Results showed that a standard course of topical fluorouracil, 5%, cream did not result in detectable improvement of photodamage on any of the photonumeric scales. Previous studies had suggested otherwise, leading authors to note that their result may be due to the fact that the scales they used were not sensitive enough to measure the effect of a standard course of treatment with topical fluorouracil. The scales used in this study were focused on rhytides and static lines in the skin. However, future studies may want to consider scales focused on lentigines, hyperpigmentation, and telangiectasias.

Dermcast.tv Blog Post: January 22, 2018
Source: JAMA Network
Adapted from the original article.

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NOTES from your Office Manager

Discontinuing The Physician–Patient Relationship Properly

THE RISK: Once the physician-patient relationship is established, providers have a legal and ethical obligation to provide patients with care. However, there may be circumstances when it is no longer appropriate to continue the physician-patient relationship. A provider may choose to discharge a patient for a variety of reasons such as non-compliance with treatment, failing to keep appointments, or inappropriate behavior. Properly discharging a patient from care can be a complex issue. In order to avoid allegations of abandonment, providers should consider establishing a formal process for discharge.

RECOMMENDATIONS:

1. The discharge of each patient must be determined by the provider on an individual basis and based on medical record documentation of patient non-compliance or disruption. We recommend that you contact your practice's legal team for specific advice.
2. A formal patient discharge should be made in writing. You must give the patient at least 30 days from the date of the letter to call you for an emergency in order to avoid charges of abandonment. This time period may be longer depending on the patient's condition and the availability of alternative care.
3. The three most common reasons why providers discharge patients are:
   - Nonpayment;
   - Noncompliance with the physician's recommendations; and
   - Disruptions in the physician-patient relationship.
4. The discharge is to be effective the date of the letter.
5. Refer the patient to the local county medical society, their health insurer, or a hospital referral source to obtain the names of other healthcare providers..
6. Provide the patient with prescriptions for an adequate supply of medication or other treatment during the 30-day emergency period.
7. Use the USPS certificate of mailing procedure, not certified mail, to send the discharge letter so it cannot be refused/unclaimed by the patient, and it can be forwarded if the patient has moved.
8. When the patient to be discharged is in need of urgent or emergent care or continuous care without a gap, is more than 24 weeks pregnant, or has a disability protected by state and federal discrimination laws, the question of whether the patient can be discharged should first be discussed with counsel since discharge may not always be possible.
9. Become knowledgeable about the requirements regarding any restrictions on discharge imposed by the third party payors with whom you participate.
10. Promptly send the patient's records to the patient's new healthcare provider upon receipt of a proper authorization.
11. Flag the office computer or other appointment system in use to avoid giving the patient a new appointment after discharge.
12. Document the problems that have led to the discharge in the patient's record. Form letters and a memorandum on the discharge of patients should be available from your practice's legal team.

Outside & Inside the 9 to 5...

Krista Smith Shares Her Experience At Camp Wonder 2017

As a proud supporter, the DPAF is thrilled to have been able to make a monetary contribution to Camp Wonder as well as to be able to send PAs to serve as volunteers. One of our volunteers was PA, Krista Smith, PA-C. She experienced firsthand how Camp Wonder provides kids with skin diseases a safe space to have fun and be a kid while having the full medical attention around the clock. Ms. Smith shares her reflections about her experience in the letter featured below.

"Camp Wonder," hearing the name alone, begs the question, "What is Camp Wonder all about?" That is precisely what I am excited to share, given that I recently returned from the camp and was able to experience the "wonder" of it all firsthand.

Imagine that you are a kid or adolescent, faced with a rare, debilitating, and possibly fatal skin disease, that you live with on a daily basis, always present, and incurable. Not only do you feel it's constant presence, often experiencing excruciating pain, burning, itching, dry eyes, trouble swallowing, blisters, etc. It is visible, staring you in the face every time you look in the mirror or down at your very own hands. This is not a hidden disease; it is not only there for you to see, but it also there for the world to see, and there is no hiding from it or running from it. Meanwhile, as you suffer the physical effects, you are also unable to escape the stares, the avoidance of others, the questions, the bullying, and often the isolation that comes from it. Our skin is our largest organ and it is meant to protect us from harm, yet it can also cause us physical and emotional pain.

Now imagine a place, a refuge, and an escape, from the daily hardship that you experience. A place where you can be yourself and be seen, liked, admired, respected, and celebrated for what is inside your heart, and not what you look like on the outside. Where you can play carnival games, eat cotton candy, swim, do arts and crafts, make s'mores, perform skits or be in a talent show, go on a scavenger hunt, climb the rock wall, ride horses, and go to the prom. All in one week, in a safe, caring, and judgment free environment. Where you see tears replaced by smiles, hearts being healed, strong friendships being made, bonds that will never be broken and where acceptance and love are the norm….That is what Camp Wonder is.

I had the privilege and honor of volunteering in 2017 at Camp Wonder, as part of the medical team, on behalf of the Dermatology PA Foundation (DPAF) and Society of Dermatology Physician Assistants (SDPA). The DPAF is a wonderful nonprofit organization, whose mission is to provide education, research to dermatology PAs, as well as to help dermatology PAs expand philanthropic activities to help and give back to others.

I first heard about Camp Wonder, from Dr. Stefani Takahashi, who is the medical co-director of the camp, (along with Dr. Jenny Kim), who was my supervising physician from 2007-2013. I witnessed firsthand, the excitement and passion she had for the camp. She frequently would talk about stories of camp and showed me pictures, and as I would listen and I observed her love for the camp, my interest grew.

At that time I had two young boys that made it difficult to leave for a week, but I always knew it was not "if," but "when" I would be able to volunteer.

Last year, it became possible for me, to go, and with my family's unwavering support behind me, I set off to experience Camp Wonder for myself.

Admittedly, I was a little nervous. Even with 14 years working as a dermatology PA-C behind me, I knew that there would be skin conditions that I had never seen in real life, but had only read about in textbooks, such as ectodermal dysplasia and Netherton syndrome. I was worried I wouldn't know what to do, or how I could help, but my worries were quickly absolved once I arrived and met the kind medical staff whose hearts were bigger than life itself, and they were not worried about my scope of knowledge, but instead, only that I was there to help.

Though I felt a little green, my motto was "put me to work," and before I knew it, I was learning the ropes about how the "med shed" operates, how to do GI-tube feedings, and what I should expect during a 3 hour dressing change for the campers with Epidermolysis Bullosa (EB).

From the get go, I was greeted with lots of friendly smiles and sensed the sincerity of all the people volunteering, from the administration, the doctors, the camp counselors, to the nurses, and residents. I got to spend some time getting to know Francesca Tenconi, the Chairman of the camp and learned of her journey with a rare skin disease, and how that shaped who she is and her passion for founding Camp Wonder.

The length of time also struck me, many of the volunteers and campers (many of whom are now counselors) had been involved with the camp. It was not unusual to hear that many such volunteers had been coming back annually, since the camp's inception.

The moment I began seeing the campers arrive I experienced firsthand why volunteers come back year after year. Seeing the smiles on the faces of the campers, and hearing the excitement in their voices, was all it took. It took all but a minute, and I was sold for life.

The week was filled with so many activities, and special moments, however, there were two that stood out to me and can't help but want to highlight and share.

The first, was when a ten-year-old girl, named Amaya, was trying to pick out her prom dress, on the rack of donated dresses (which is another wonderful testimony of the camp and all those involved!), but she was having a hard time finding one that fit. She looked sad and discouraged; she wanted to give up. However, a kind resident named Dorota, and I were determined to help her find something that she liked and felt special in, for the prom, that would be held at the end of the week. After some searching, Amaya finally found the dress. However, the straps were too long for her. Given that I can suture, I offered to sew the straps for her so that it would fit her properly. She was so grateful, and for the first time I saw her sigh a sigh of relief, and she gave a big smile. On a grand scale, my actions were not much, but sometimes it is those little moments and the small things that make your heart swell up with joy. Knowing that doing a little something extra for her, was all it took to make her feel confident for her prom, and for me, being part of that what priceless.

Another memorable moment for me was getting to see the kids participate in karaoke. It was a hot day, right after lunch and several of the campers were seeking refuge from the heat, and hanging out in the activities center. I grabbed the karaoke machine, and turned it on, disco lights flashing and all, and started taking song requests. At first, several of the campers just listened to the music, and held the microphone, shyly singing, when all of the sudden, a girl named Lexi, took the stage stole the show. She got the party started by singing "Party in the USA," all the while, dancing, and smiling ear to ear. Her energy was contagious, and before you knew it, the whole audience was clapping along and singing too. After her performance, the excitement for karaoke grew, and it became a hit, and many songs were sung and dancing broke out for a great deal of time. Many of the campers asked for karaoke the next day and no one was shy after that. It was a huge hit. Lexi stole the show and my heart!

I came home from camp with stories upon stories like the ones I described above, but until you experience it for yourself, it is just a story, and it is impossible to describe the "wonder" of it all until you are part of it firsthand.

I cannot encourage you enough to volunteer and make your own stories at Camp Wonder, by making a difference in the life of someone today! I am better because of Camp Wonder and will be forever changed.

Until next year Camp Wonder…I'll be seeing you again!

-Krista S.

The DPAF is so grateful to Krista and all of our supporters who make it possible for us to contribute to Camp Wonder as well as our many other philanthropic activities.

Photos taken by Krista Smith and printed with permission from Children's Skin Disease Foundation.

Workplace Excellence

Coaching on Goal Achievement Process - Part 1 of 2

By Matthew Davidson, PhD

In my work as President of the Institute for Excellence & Ethics (IEE) I have had the opportunity to work with diverse individuals and organizations in their quest to achieve excellence. This column dedicated to workplace excellence explores the organizational, interpersonal, and ethical issues that contribute to (or detract from) individual or organizational excellence within the physician assistant profession. If you have any workplace topics you would like to see covered in the JDPA please feel free to share them with us. Email editor@jdpa.org with any topic ideas or questions concerning the workplace.

Don't make a list of titles, accolades, or awards you want to get. Make a detailed plan on how you'll get from where you are now to where you want to be. This is the core coaching/managing message around the Goal Achievement Process. Too often we make a list of goals we hope to achieve and call it "goal setting". But we're talking about ***goal achievement,*** NOT *goal setting.* It doesn't matter if the list of goals is Specific, Measureable, Attainable, and Timely. Goal achievement is a process that involves more than making a detailed list.

No matter what we are trying to achieve, no matter what challenge we are trying to overcome, the goal achievement process begins by clarifying the *starting point* and the ***desired end-goal.*** Then the process requires identifying the major ***action steps*** to go from the starting point to the end-goal, and breaking them further into smaller, more detailed steps. Once the plan is put into action, the process requires that we must continuously measure and monitor our progress and make changes and adjustments as needed. Finally, the goal achievement process requires support and challenge from individuals who are able to provide the required ***expertise, accountability, and encouragement.***

COMMUNICATION

Coaching for optimal performance on goal achievement starts with making sure that those we're working with have a very detailed and accurate self-assessment of their starting point. If you want to be able to check in, efficiently transcribe, and properly bill EMR notes for 30 patients a day, then knowing what your past personal best is essential -saying it's 25, when it's 10, doesn't help calibrate the steps to the goal. The goal achievement that your particular office is focusing on can involve a wide variety of topics ranging from staffing, patient care, provider efficiency, scheduling, and any other pressing topics. Coaching for optimal performance requires ongoing dialogue and communication to determine what an optimal response looks, sounds, and feels like, in pursuit of one's goals. Information gathered from surveys/interviews with patients and/or healthcare provider teams can lend insight into topics to focus energy on.

Communication around the ***Goal Achievement Process*** means reinforcing the need for maps that are calibrated with the right details for the particular goal being pursued. A ***goal map*** of your life goals would look very different than a goal map on how to finish your first marathon, or a map for going from a D to an A in a class. As the saying goes, "Details are what stand between most people and the achievement of their goals." Communication for optimal performance also means reinforcing the need for continuous recalibrating and adjustment of the action steps. Like a plane trying to fly from point A to point B and needing to adjust for wind, weight, etc., managers/healthcare providers must continuously stress the need for making the proper adjustments to the required action steps, and getting back on the path to the end goal as quickly as possible. Just like getting lost in your car, it's not the end of the world to get a little lost in pursuit of your goals. A key message for managers/healthcare providers to communicate is vigilant monitoring of the plan, and quickly adjusting the plan as soon as you're off track.

HABIT

The ***Goal Achievement Process*** is an active process, a habit, a skill. And likeany other skill, it won't work for you unless you work at mastering it. Knowledge about how to make a goal map isn't the same thing as mastering the habit of achieving your goals. The best map won't get you to your destination; it provides the route, but you must follow it. What this means for optimal performance coaching is that the goal achievement process must be practiced in numerous and varied ways: daily goals, weekly goals, goals for the season, goals for today's workday, goals for the entire healthcare team, goals for the healthcare providers/staff members/practice, personal goals, and life goals. Goal achievement becomes a habit, a way of consistently behaving, only when it is practiced continuously, not just occasionally.

Experiencing success around some smaller goals builds confidence for larger goals. The steps are the same, but bigger goals require more patience and perseverance, a more complex set of action steps, and far more adjustments of the goal map plan. So, just like with sport skills, we grow in strength and competence in our skills the more we practice. There are numerous opportunities to practice the goal achievement process - for individual staff members and the entire healthcare team. But the key is not simply to practice forming the habit of goal-setting. Goal achievement has a lot more pieces that require practice after setting goals: breaking down into pieces, measuring, monitoring, seeking and giving support, making adjustments - all of these are skills that become habits through intentional practice.

ACCOUNTABILITY

Accountability is an essential piece of the ***Goal Achievement Process.*** Goal setting may be an individual activity, but goal achievement requires the support and challenge of qualified coaches/managers. The support and challenge each healthcare member needs depends on their current state and their desired end-goal. The key for coaches/managers is to help members of the team know how and when to ask for help in pursuit of their goals. The more lofty the goals, the more important the accountability. As the saying goes, "The journey of a thousand miles begins with the first step." Oftentimes it's the accountability provided by a coach/manager or fellow staff member that ensures that members take the first step (or the next essential step) in pursuit of their goals.

Part of the accountability and expertise that coaches/managers must be able to provide are the insights around when and how to make adjustments. There is an art and science to goal achievement, one that balances perseverance with prudence, a sense of when to stay the course and when to adjust or abandon

the plan. As we work on our goal maps and begin implementation, adjustments will be required. Wrong turns will be made. Circumstances may change. An illness or injury, a family situation, a change in coaches/managers - there are nearly unlimited factors that impact the pursuit of a goal. That is why it is so essential to measure and monitor your progress along the way, and be ready to revise as needed.

Healthcare providers/teams must have numerous, varied, and timely measurement of their goal process. Some measurements are simple: did you do it or not? If not, why? If yes, then what's the next step? Others require measurement that is more specific, like using a spreadsheet to monitor times, or keeping track of patient feedback relating to office visits. Others require optimal performance indicators to help to define unclear steps or concepts within a goal map, for example "improve attitude", "give maximum effort", or "stay positive." If these are defined they can be measured. If they can't be measured, you can't know if you're making progress or whether or what to adjust. In order to provide accountability coaches/managers must help heathcare providers/teams refine and define detailed ways to measure and monitor.

MINDSET

There is no one right pathway to most of the goals that individuals pursue. Too often when individuals take on a goal they are plagued by comparison to others, or by comparison to how they think the process will unfold. Therefore, coaching/managing for mindset around the Goal Achievement Process needs to focus on the right preparation, on emotional toughness, and on quick recovery. As the saying goes, "No plan can long survive contact with the enemy." So too with most of our goal maps. Therefore, coaches/managers must help healthcare providers and office teams to visualize implementation - in the ideal, and all other variations including the good, the bad, and the disastrous.

Coaches/managers should continuously reinforce that pilots are "off-course" most of the time. They have a perfect plan from here to there, but they are mostly off that and adjusting continuously to get close to the optimal. When it comes to goal achievement, coaching/managing for optimal performance means preparing healthcare providers/teams to not let perfect be the enemy of good enough. Goal achievement mindset is all about committing to the process: define current and desired state; measure, monitor, and adjust; seek expertise, encouragement and accountability; repeat.

It's hard to estimate how long it will take to accomplish any goal we set for ourselves. For some it may be a direct path and a tight timeline, for others it may be a journey with lots of detours that takes a little longer. Mistakes and wrong turns aren't the end of the world as long as you're learning, growing, and improving yourself on the path to your goal. Coaching/managing is about helping those we supervise to keep their eye on the desired destination, and continuously adjusting and refining their action steps. Finally, we must never forget that we learn and grow on the journey - not just when we arrive at our destination. Zig Ziglar famously said, "What you get by achieving your goals is not as important as what you become by achieving your goals."

EXPERTISE, ENCOURAGEMENT, ACCOUNTABILITY

No matter what you're trying to achieve, no matter what challenge you're trying to overcome, you need to start by figuring out your current position (or starting point) and your desired destination (or end goal). Then you need to identify the action steps to get you from your starting point to your end goal, breaking them into small steps. Once the plan is put into action you must continuously measure and monitor your progress and make changes as needed. You also need to seek out support and challenge from individuals who are able to provide you with expertise, accountability, and encouragement.

Matthew L. Davidson, Ph.D. is the Founder, President, and Director of Education for the Institute for Excellence & Ethics (IEE), a 501(c)3 nonprofit corporation dedicated to helping individuals and organizations achieve excellence. He is a National Spokesperson for the Business Bureau National Center for Character Ethics. The IEE specializes in the development and dissemination of research-based tools for developing the culture and competencies of excellence and ethics in schools, athletics, the workplace, and the home; this is done through professional development workshops & academies, teaching & learning resources, assessment, and consulting services. He is a frequent national presenter and is available for keynote lectures, professional development, retreats, and organizational consulting. He has indicated no relationships to disclose relating to the content of this article. For additional information or to contact the IEE, please visit www.excellenceandethics.org.

The Only FDA Approved Clobetasol Propionate 0.025%

IMPOYZ™ (clobetasol propionate) Cream 0.025% is indicated for the treatment of moderate to severe plaque psoriasis in patients 18 years of age and older.[1]

impoyz™
(clobetasol propionate)
Cream, 0.025%

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

Topical corticosteroids, including IMPOYZ Cream can cause reversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for glucocorticosteroid insufficiency. This may occur during treatment or after withdrawal of treatment. This may require that patients be evaluated periodically for evidence of HPA axis suppression. Factors that predispose to HPA axis suppression include, use of high-potency steroids, large treatment surface areas, prolonged use, use of occlusive dressings, altered skin barrier, liver failure, and young age. If HPA axis suppression occurs, gradually withdraw the drug, reduce frequency of application, or substitute with a less potent corticosteroid. If signs and symptoms of withdrawal occur, systemic corticosteroids may be required. Recovery of HPA axis function is generally prompt and complete upon discontinuation of topical corticosteroids. Although rare, systemic effects of topical corticosteroids may manifest as Cushing's syndrome, hyperglycemia, and glucosuria. Pediatric patients may be more susceptible to systemic toxicity because of their larger skin surface to body mass ratios. **Local Adverse Reactions with Topical Corticosteroids -** Local adverse reactions from topical corticosteroids may be more likely to occur with occlusion, prolonged use, or use of higher potency corticosteroids. Some local adverse reactions may be irreversible. **Concomitant Skin Infections -** Use an appropriate antimicrobial agent if a skin infection is present or develops. If appropriate, discontinue use of IMPOYZ Cream. **Allergic Contact Dermatitis -** Allergic contact dermatitis with corticosteroids is usually diagnosed by observing failure to heal rather than noting a clinical exacerbation. **Adverse Events -** The adverse reaction that occurred in at least 1% of subjects treated with IMPOYZ Cream and at a higher incidence than in subjects treated with vehicle cream was application site discoloration (2% versus 1%). Less common local adverse events occurring in < 1% of subjects treated with IMPOYZ Cream were application site atrophy, telangiectasia and rash.

1. Impoyz Cream full Prescribing Information.

Please see Brief Summary of Full Prescribing Information on the following pages.

CLB1214 4/18

This Brief Summary does not include all the information needed to use IMPOYZ safely and correctly. See full Prescribing Information.
IMPOYZ (clobetasol propionate) Cream, 0.025%, for topical use

INDICATIONS AND USAGE

IMPOYZ Cream 0.025% is indicated for the treatment of moderate to severe plaque psoriasis in patients 18 years of age and older.

DOSAGE AND ADMINISTRATION

Apply a thin layer of IMPOYZ Cream to the affected skin areas twice daily and rub in gently and completely. Use IMPOYZ Cream for up to 2 consecutive weeks of treatment. Treatment beyond 2 consecutive weeks is not recommended, and the total dosage should not exceed 50 g per week because of the potential for the drug to suppress the hypothalamic-pituitary-adrenal (HPA) axis [see Warnings and Precautions (5.1)]. Discontinue IMPOYZ Cream when control is achieved. Do not use if atrophy is present at the treatment site. Do not bandage, cover, or wrap the treated skin area unless directed by a physician. Avoid use on the face, scalp, axilla, groin, or other intertriginous areas. IMPOYZ Cream is for topical use only. It is not for oral, ophthalmic, or intravaginal use. Wash hands after each application.

DOSAGE FORMS AND STRENGTHS

Cream, 0.025%: each gram contains 0.25 mg of clobetasol propionate in a white to off-white cream base.

CONTRAINDICATIONS. None

WARNINGS AND PRECAUTIONS

Effects on the Endocrine System: IMPOYZ Cream can cause reversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for glucocorticosteroid insufficiency. This may occur during treatment or after withdrawal of treatment. Because of the potential for systemic absorption, use of topical corticosteroids, including IMPOYZ Cream, may require that patients be evaluated periodically for evidence of HPA axis suppression. Factors that predispose a patient to HPA axis suppression include the use of high-potency steroids, large treatment surface areas, prolonged use, use of occlusive dressings, altered skin barrier, liver failure, and young age. Evaluation for HPA axis suppression may be done by using the adrenocorticotropic hormone (ACTH) stimulation test. In a trial evaluating the effects of IMPOYZ Cream on the HPA axis, subjects with plaque psoriasis applied IMPOYZ Cream twice daily to at least 20% of involved Body Surface Area (BSA) for 15 days. Abnormal ACTH stimulation tests suggestive of HPA axis suppression were seen in 3 of 24 (12.5%) subjects on IMPOYZ Cream [see Clinical Pharmacology (12.2)]. In another trial to evaluate the effects of IMPOYZ Cream on the HPA axis, subjects with moderate to severe plaque psoriasis applied IMPOYZ Cream twice daily to at least 25% of involved BSA for 28 consecutive days. Abnormal ACTH stimulation test suggestive of HPA axis suppression was seen in 8 of 26 (30.8%) of subjects on IMPOYZ Cream. If HPA axis suppression is documented, gradually withdraw the drug, reduce the frequency of application, or substitute with a less potent corticosteroid. If signs and symptoms of steroid withdrawal occur, supplemental systemic corticosteroids may be required. Recovery of HPA axis function is generally prompt and complete upon discontinuation of topical corticosteroids. Systemic effects of topical corticosteroids may also manifest as Cushing's syndrome, hyperglycemia, and glucosuria. These complications are rare and generally occur after prolonged exposure to larger than recommended doses, particularly with high-potency topical corticosteroids. Use of more than one corticosteroid-containing product at the same time may increase the total systemic exposure to topical corticosteroids. Minimize the unwanted risks from endocrine effects by mitigating risk factors favoring increased systemic bioavailability and by using the product as recommended [see Dosage and Administration (2)]. Pediatric patients may be more susceptible to systemic toxicity because of their larger skin surface to body mass ratios [see Use in Specific Populations (8.4)].

Local Adverse Reactions with Topical Corticosteroids

Local adverse reactions from topical corticosteroids may include atrophy, striae, telangiectasias, burning, itching, irritation, dryness, folliculitis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, secondary infection, and miliaria. These may be more likely to occur with occlusive use, prolonged use, or use of higher potency corticosteroids, including IMPOYZ Cream. Some local adverse reactions may be irreversible.

Concomitant Skin Infections: Use an appropriate antimicrobial agent if a skin infection is present or develops. If a favorable response does not occur promptly, discontinue use of IMPOYZ Cream until the infection has been adequately treated.

Allergic Contact Dermatitis: Allergic contact dermatitis with corticosteroids is usually diagnosed by observing failure to heal rather than noting a clinical exacerbation. Such an observation should be corroborated with appropriate diagnostic patch testing. If irritation develops, discontinue the topical corticosteroid and institute appropriate therapy.

ADVERSE REACTIONS

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug, and may not reflect the rates observed in practice. IMPOYZ Cream was evaluated in two randomized, multicenter, prospective, vehicle-controlled clinical trials in subjects with moderate to severe plaque psoriasis. Subjects applied IMPOYZ Cream or vehicle cream twice daily for 14 days. A total of 354 subjects applied IMPOYZ Cream and 178 subjects applied vehicle. The adverse reaction that occurred in at least 1% of subjects treated with IMPOYZ Cream and at a higher incidence than in subjects treated with vehicle cream was application site discoloration (2% versus 1%). Less common local adverse events occurring in < 1% of subjects treated with IMPOYZ Cream were application site atrophy, telangiectasia and rash.

Postmarketing Experience

The following adverse reactions have been identified during post-approval use of clobetasol propionate: striae, irritation, dryness, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, secondary infection, hypertrichosis, and miliaria. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

USE IN SPECIFIC POPULATIONS

Pregnancy: Risk Summary There are no available data on IMPOYZ Cream in pregnant women to inform a drug-associated risk for adverse developmental outcomes. Published data report a significantly increased risk of low birthweight with the use of greater than 300 grams of potent or very potent topical corticosteroid during a pregnancy. Advise pregnant women of the potential risk to a fetus and to use IMPOYZ Cream on the smallest area of skin and for the shortest duration possible (see Data). In animal reproduction studies, increased malformations, such as cleft palate and skeletal abnormalities, were observed after subcutaneous administration of clobetasol propionate to pregnant mice and rabbits. No comparisons of animal exposure with human exposure are provided due to minimal systemic exposure noted after topical administration of IMPOYZ Cream [see Clinical Pharmacology (12.3)]. The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Data

Human Data

Multiple observational studies found no significant associations between maternal use of topical corticosteroids of any potency and congenital malformations, preterm delivery, or fetal mortality. However, when the dispensed amount of potent or very potent topical corticosteroid exceeded 300 g during the entire pregnancy, use was associated with an increase in low birth weight infants [adjusted RR, 7.74 (95% CI, 1.49–40.11)]. In addition, a small cohort study, in which 28 sub-Saharan women using potent topical corticosteroids (27/28 used clobetasol propionate 0.05%) for skin lightening during pregnancy, noted a higher incidence of low birth weight infants in the exposed group. The majority of exposed subjects treated large areas of the body (a mean quantity of 60 g/month (range, 12–170g) over long periods of time.

Animal Data

In an embryo fetal development study in mice, subcutaneous administration of clobetasol propionate resulted in fetotoxicity at the highest dose tested (1 mg/kg) and malformations at the lowest dose tested (0.03 mg/kg). Malformations seen included cleft palate and skeletal abnormalities. In an embryofetal development study in rabbits, subcutaneous administration of clobetasol propionate resulted in malformations at doses of 0.003 and 0.01 mg/kg. Malformations seen included cleft palate, cranioschisis, and other skeletal abnormalities.

Lactation: Risk Summary There is no information regarding the presence of clobetasol propionate in breast milk or its effects on the breastfed infant or on milk production. Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. It is not known whether topical administration of clobetasol propionate could result in sufficient systemic absorption to produce detectable quantities in human milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for IMPOYZ Cream and any potential adverse effects on the breastfed infant from IMPOYZ Cream or from the underlying maternal condition. Clinical Considerations: To minimize potential exposure to the breastfed infant via breast milk, use IMPOYZ Cream on the smallest area of skin and for the shortest duration possible while breastfeeding. Advise breastfeeding women not to apply IMPOYZ Cream directly to the nipple and areola to avoid direct infant exposure.
Pediatric Use: The safety and effectiveness of IMPOYZ Cream in patients younger than 18 years of age have not been established; therefore, use in children younger than 18 years is not recommended. Because of a higher ratio of skin surface area to body mass, pediatric patients are at a greater risk than adults of systemic toxicity, including HPA axis suppression, when treated with topical drugs [see Warnings and Precautions (5.1)]. Rare systemic toxicities such as Cushing's syndrome, linear growth retardation, delayed weight gain, and intracranial hypertension have been reported in pediatric patients, especially those with prolonged exposure to large doses of high potency topical corticosteroids. Local adverse reactions including striae and skin atrophy have also been reported with use of topical corticosteroids in pediatric patients. Avoid use of IMPOYZ Cream in the treatment of diaper dermatitis.
Geriatric Use: Clinical studies of IMPOYZ Cream did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience with topical corticosteroids has not identified differences in responses between the elderly and younger patients.
NONCLINICAL TOXICOLOGY Carcinogenesis, Mutagenesis, Impairment of Fertility: Long-term animal studies have not been performed to evaluate the carcinogenic potential of clobetasol propionate cream. In a 13-week repeat dose toxicity study in rats, topical administration of clobetasol propionate cream, 0.001, 0.005 and 0.025 % at corresponding doses of 0.004, 0.02 and 0.1 mg/kg/day resulted in corticosteroid class-related systemic effects such as reductions in body weight gain, reductions in total leukocytes and individual white cells, decrease in weight of adrenals, thymus, spleen, liver and lung. Histologically, there were decreased hematopoiesis in the bone marrow, thymic atrophy and mast cell infiltration of the mesenteric lymph nodes. All these effects were indicative of severe immune suppression consistent with long-term exposure to corticosteroids. A no observable adverse effect level (NOAEL) was determined to be clobetasol propionate cream, 0.001% (0.004 mg/kg/day) in male rats while a NOAEL could not be determined in females. The clinical relevance of the findings in animals to humans is not clear, but sustained glucocorticoid-related immune suppression may increase the risk of infection and possibly the risk of carcinogenesis. Clobetasol propionate was not mutagenic in three different test systems: the Ames test, the Saccharomyces cerevisiae gene conversion assay, and the E. coli B WP2 fluctuation test. Fertility studies conducted in the rat following subcutaneous administration of clobetasol propionate at dosage levels up to 0.05 mg/kg/day revealed that females exhibited an increase in the number of resorbed embryos and a decrease in the number of living fetuses at the highest dose.

Manufactured by DPT Laboratories Ltd., San Antonio, TX 78215 For Encore Dermatology, Inc., Scottsdale, AZ 85254

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The Difference We Make

Rediscovering the Joys of Medicine - Dealing With and Healing from Burnout

By Steven Shama, MD, MPH, FAAD

Do you feel that you've lost the enjoyment of your practice, the joy that you once had? Have you felt more psychologically and physically tired each day than you used to, do you question your worth as a clinician, and are you apathetic and disillusioned about your future? Join 50% of your physician assistant colleagues and a similar percentage of physicians of all medical and surgical specialties who are experiencing the toxic environment of practicing medicine today and the consequent sufferings of burnout.[1,2]

Twenty-five years ago I recall experiencing burnout, feeling overwhelmed, believing that I was being taken advantage of by the "system" with regard to fair monetary compensation, and judging that I was underappreciated by my hospital. Fortunately, I was able to overcome burnout by techniques that have recently been popularized and recognized to be effective.

The reasons you should care about burnout are because it is all around you and because it may determine how effective you and your colleagues are as clinicians.

Burnout erodes the very fabric of medical practice; it leads to unhappy clinicians and patients, poor outcomes, medical mistakes, depression, suicides, drug addiction, and the premature retirement of the best of us.

This article will define burnout, describe whom it affects, explain how we can recognize it, explore its causes, and suggest what can we do about it.

Defining Burnout

Burnout is composed of the following three symptoms:

1. **Emotional exhaustion** - This is the result of chronic stress. "I'm tired all the time, emotionally and physically, and I've lost my enthusiasm to work. I'm constantly overwhelmed."
2. **Feelings of cynicism** - depersonalization- People attempt to put distance between themselves and the stressors. "I don't like seeing patients and am seriously considering leaving my practice entirely."
3. **Professional inefficacy** - This is the result of exhaustion and cynicism. "I'm not proud of what I'm doing anymore."[3]

Whom Does Burnout Affect?

The following statistics are for physicians who have been studied with regard to burnout for many years. Only recently have researchers begun to evaluate physician assistants, but there is enough preliminary evidence from articles that the burnout rate of physician assistants in general is similar to the burnout rate of the general physician population.[1,2]

Rates of burnout amongst physician specialties[4]

- Highest-Emergency Room Medicine 59%
- Lowest-Psychiatry 42%
- Dermatology 46% (up from 32% in 2011).
- The happiest physicians at work are dermatologist at 39%. [Consider that essentially 59% of dermatologists are NOT happy at work.]
- The least happy physicians at work are in internal medicine at 24%.
- The highest risk of burnout is in physicians less than 35 years of age.
- 30% of primary care physicians 35 to 39 years of age plan to leave their practice in less than five years.
- 50% of primary care physicians greater than 50 years of age plan to leave their practice in less than five years.[5]

How Do We Recognize Burnout In Ourselves?

If we are having any of the following thoughts on a frequent basis we may be close to burnout:

- I'm tired of coming to work.
- I see patients as an intrusion into my day.
- I don't care about attention to details.
- I feel taken advantage of by the system
- No one listens to me.
- I'm overwhelmed.
- I want to quite medicine altogether.

How Do We Recognize Burnout On An Institutional Level?

Symptoms of burnout at an institutional level include:

- Decreased attendance at meetings
- Demands from frustrated physicians for compensation for everything they do
- Angry complaints about the electronic medical record
- High staff turnover

According to Christine Maslach who originally coined the term burnout in the late 1980s, burnout develops when there is a mismatch between the job and the person. Maslach states, along with many other investigators, that the problem of burnout lies not with the clinician, but with the system.

1. Lack of control - Not enough control by the clinician over what he/she does, associated with feelings of being trapped.
2. Work overload - Not enough time or equipment. It has been estimated that 49% of a clinician's time is engaged in clerical work, including the electronic medical record, and only 33 % in direct clinical work.6
3. Insufficient rewards - Not enough feedback that you are doing a good job.
4. Absence of fairness - Decisions about your professional life need to be fair.
5. Conflict of Values - The clinician's primary responsibility is to the patient instead of the organization; with the latter, finances often are the primary concern.
6. Breakdown of workplace community - Little trust among staff members.[7]

How Do We Effectively Deal With Burnout?

How can we make working in the health care system healthier and less stressful and how can we rediscover the joys of medicine? First and foremost, we need to recognize and embrace the fact that we deserve to be happy. Many of us are very conscientious people and happiness often is not our goal; instead efficiency has become our new standard. We must make happiness and a satisfying, fulfilling professional life our primary goals. It is the system that must be changed. We need to take back medicine, re-establish the sacred times we spend with our patients, and not have cost or time as our primary restraints.

I suggest ten approaches in dealing with burnout if you or a colleague has symptoms:

1. Join your state and/or national professional societies and their committees working on this issue or select colleagues to represent you.
2. Approach your hospital administrators with your concerns, and enlist the support of your colleagues, regardless of their specialties.
3. Ask your administrators for realistic and sustainable workloads including a realistic patient schedule.
4. Ask your organization to involve you in decisions that directly affect you and your practice of medicine.
5. Ask your organization to be treated fairly and to be valued for your opinion.
6. When your basic values and your organization's values seem to be at odds, bring this to the attention of your administrators.
7. Take care of your self. Remember to take a break whether it's midmorning, midafternoon, during the week, or on weekends. Consider self-help programs such as the "Steps Forward Program" by the AMA, consider a program set up by your hospital institution, or seek private help.
8. Reconnect with your patients. Remember to be present with them with less concern about time and to listen to understand rather than simply hearing and recording. Make sure that you always maintain that sacred trust between you and your patient and that you always leave them with hope.
9. Reconnect with your colleagues. Appreciate them for who they are, not only for what they do in medicine. Send them a letter to thank them for the good work that they do and for being available for you. Give them a call and tell them how much you appreciate them and don't connect that call to a patient follow-up. Donate to a charity in their name to honor them.
10. Reconnect with your family and friends. Know that they will always love you and appreciate you probably more than you will ever appreciate yourself.

Conclusion

If after reading this article you believe you may have symptoms of burnout, now is the time to get help. If you came into medicine and specifically dermatology because you love to be a healthcare provider and you love dermatology, never let burnout erode that joy. If you know of someone with whom you work or a colleague of yours outside of your office who may have symptoms of burnout, befriend that person and suggest that you have a solution that very well may bring back their joy.

Never forget that you deserve to be happy and you deserve to smile. This is a truth. Your family, friends, colleagues, and your patients need you to be fully present, ready to be a good listener, and able to care and give hope. Be kind to yourself. Never allow a system that only knows how to demand efficiency and that has no soul to get in the way of your essence as a clinician.

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Dr. Steve Shama *was practicing general dermatology for 30 years in Boston, Massachusetts until last year. He retired at that time but continues in a 20 year career as a professional speaker and enjoys speaking on topics such as, "Dealing With Difficult People and Looking Forward To It!" and "Rediscovering The Joys of Medicine and of Life." He gives these talks at medical meetings, in private practices, and to general audiences and youth throughout the country. You can reach Dr. Shama at www.steveshama.com.*

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From the Desk of...

Joleen Volz, MPAS, PA-C, DFAAPA
SDPA President-Elect

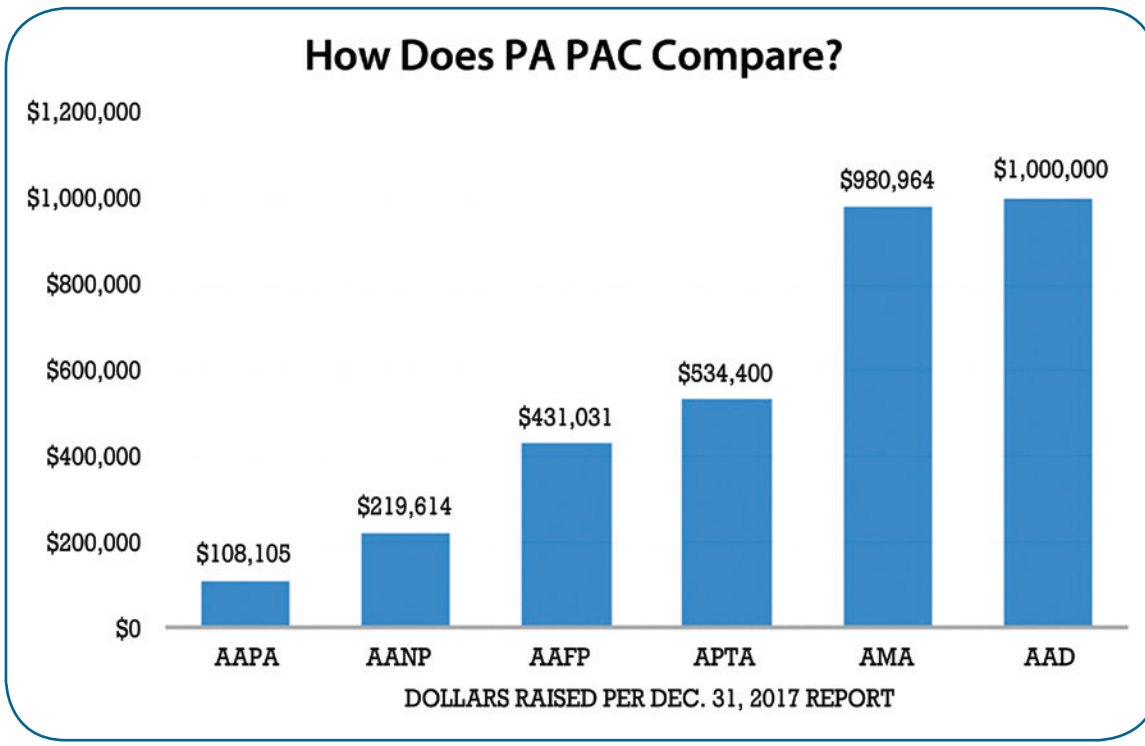
Support the AAPA's Political Action Committee

Recently, several SDPA leaders attended the 2018 AAPA Leadership and Advocacy Summit in Washington, D.C.. The event began with a full day dedicated to federal advocacy, as well as afternoon visits on Capitol Hill. The remainder of the event included sessions that were focused on advancing Optimal Team Practice, advocacy skill-building, and best practices for constituent organization leaders. I found this meeting to be very enlightening. It was one of my first experiences with advocacy and opened my eyes to how important it is to not only be members of our national society, AAPA, but also the importance of donating to the PA Political Action Committee that so diligently represents our profession on Capitol Hill.

A Political Action Committee (PAC) is an organization that privately raises campaign contributions from members and then donates those monies to positively impact elections, or in our case legislation, especially at the federal level.

The PA PAC is a bipartisan political action committee of the AAPA. It is the only federal PAC that is dedicated to advancing the PA profession. The mission of the PA PAC is to allow individual PAs to share in the opportunity to support federal candidates for Congress who have demonstrated their belief and understanding of the principles to which the PA profession is dedicated.

There has never been a more important time in our profession's history than now to donate to our national PA PAC. We need to take action to support legislation and remove the barriers to PA practice. Optimal Team Practice is needed for the future of the PA profession. Every PA has the responsibility to directly impact our profession and help its forward progress. Other professions are positioning themselves to be more attractive



to employers and in turn threaten the future of the PA profession. PAs have both the education and clinical experience to be recognized as collaborative team members in our medical practices, but we need to be proactive in ensuring the long-term viability of the profession.

The PA PAC raised $108,105 from the 1,798 members and employee donors this past year. While less than 4% of AAPA members contributed in 2017, this contribution to the PA PAC is a significant increase over previous years, but is only a fraction of what is needed to achieve our professional goals. This number must continue to grow in order to have an effect on advocacy. It is important for each of us to be active members of the societies that advocate for our profession and to contribute to our PAC.

According to Open Secrets (www.opensecrets.org), which is an organization that is dedicated to transparency in politics, the PA PAC ranked 46th amongst 122 health provider group PACs. The PA PAC contributions lag considerably amongst our peers. The American Academy of Dermatology Skin PAC raised $1 million last year. The American Academy of Nurse Practitioners, the American Academy of Family Physicians, the American Physical Therapy Association and the American Medical Association all raise significantly more money per member than the PA PAC (see table).

The SDPA looked into making a significant contribution on behalf of its members but found that it would be unlawful to do so since there are legal restrictions on allocation of member funds to a PAC. It is illegal for a 501(c)6 non profit professional organization to donate to a PAC, therefore it is crucial that our members consider individual donations to the PA PAC. Regulations limit the amount any one individual can donate to a PAC to less than $5,000 per year.

The AAPA has over 56,000 members. If each member contributed just $35 (only 9 cents per day) this would put PA PAC ranked #1. The SDPA currently has 3,300 members. If we could each commit to donate $20 we could raise $66,000 just in SDPA member contributions alone to help legislate, advance and protect the future of our PA profession.

Camp Discovery 2018

Camp Discovery was founded in 1993 and offers a summer camp experience like no other. Every summer, the American Academy of Dermatology sponsors six weeks of camp in five locations where everyone can experience activities such as fishing, swimming, archery, horseback riding, nature trails, and just plain fun!

Under the expert care of dermatologists and dermatology healthcare professionals, Camp Discovery offers campers the opportunity to spend a week among other young people who have similar skin conditions. Many of the counselors have chronic skin conditions as well, and can provide support and advice to campers.

There is no fee for camp. All costs, including transportation, are provided by the American Academy of Dermatology through generous donations from its members, other organizations, and individuals. The American Academy of Dermatology is proud to offer this experience to about 380 children each year.

To attend Camp Discovery, a provider must first refer the child to the American Academy of Dermatology for admission. To refer a patient, simply download the camper referral form at www.campdiscovery.org and submit it back to the American Academy of Dermatology by email/fax. For questions, please contact jmueller@aad.org or call (847) 240-1737.

CAMP DISCOVERY 2018 Dates:

- CROSSLAKE, MINNESOTA
June 17–22, 2018 • 8–16 years old
- CROSSLAKE, MINNESOTA
July 1–6, 2018 • 8–16 years old
- BURTON, TEXAS
August 5–10, 2018 • 8–16 years old
- ANDOVER, CONNECTICUT
August 12–18, 2018 • 8–16 years old
- MILLVILLE, PENNSYLVANIA
August 11–17, 2018 • 8–16 years old

For more information about attending or volunteering please visit the Camp Discovery website at www.campdiscovery.org or contact Janine Mueller at (847) 240-1737 or jmueller@aad.org.

Collaborating Physician **CORNER**

American Academy of Dermatology Awards Twenty-six Shade Structure Grants To Protect America's Youth

Skin cancer is the most common cancer in the United States, and it only takes one blistering sunburn during childhood or adolescence to nearly double a person's chance of developing melanoma, the deadliest form of skin cancer, later in life. To help protect children and adolescents from the sun's harmful ultraviolet rays, the American Academy of Dermatology (AAD) has awarded Shade Structure grants to 26 schools and nonprofit organizations across the country.

Since its launch in 2000, the AAD's Shade Structure Grant Program has awarded 368 shade structure grants.

The structures supported by the program provide shade for more than 880,000 individuals each day.

"Sun exposure is the most preventable risk factor for skin cancer, and shade is such a simple way to reduce that risk starting at an early age," says board-certified dermatologist Suzanne M. Olbricht, MD, FAAD, President of the AAD. "The AAD is proud to help these organizations provide permanent shade structures that allow children to play outdoors while staying safe from the sun's harmful UV rays."

In addition to seeking shade, the AAD recommends that everyone protect himself or herself from the sun by wearing protective clothing and applying a water-resistant, broad-spectrum sunscreen with an SPF of 30 or higher.

The AAD awarded its 2018 AAD Shade Structure grants to the following organizations:

ALABAMA

- Buhl Elementary School, Buhl, Ala.
  Sponsored by Karen Walker, MD, FAAD
- Boys & Girls Clubs of Central Alabama Inc., Brookside, Ala.
  Sponsored by Robert Henderson Jr., MD, FAAD

ARIZONA

- Vistancia Elementary School, Peoria, Ariz.
  Sponsored by James Pehoushek, MD, FAAD
- Fremont Junior High School, Mesa, Ariz.
  Sponsored by James Young, MD, FAAD
- Carson Junior High School, Mesa, Ariz.
  Sponsored by Howard Donsky, MD, FAAD
- Mountain View Preparatory School, Cottonwood, Ariz.
  Sponsored by Carin Cain, MD, FAAD

CALIFORNIA

- CHAMPS Charter High School of the Arts, Van Nuys, Calif.
  Sponsored by Michael Lin, MD, FAAD
- Del Rey Elementary School, Orinda, Calif.
  Sponsored by Maryam Asgari, MD, FAAD
- Boys & Girls Clubs of Santa Monica, Santa Monica, Calif.
  Sponsored by Nita Patel, MD, FAAD
- Cuyamaca College Child Development Center, El Cajon, Calif.
  Sponsored by Michael Thoene, MD, FAAD

COLORADO

- Montrose Botanical Society, Montrose, Colo.
  Sponsored by Renata Raziano, MD, FAAD
- John McConnell Math and Science Center, Grand Junction, Colo.
  Sponsored by Amy Paul, MD, FAAD

- Corpus Christi Catholic School, Colorado Springs, Colo.
  Sponsored by Christopher Sartori, MD, FAAD
- Warren Tech High School, Lakewood, Colo.
  Sponsored by Harvey Arbuckle, MD, FAAD

DISTRICT OF COLUMBIA

- Robert Brent Elemenatary PTA, Washington, D.C.
  Sponsored by Scott Norton, MD, FAAD

FLORIDA

- Marco Island Academy, Marco Island, Fla.
  Sponsored by Daniel Wasserman, MD, FAAD
- J.R. Arnold High School, Panama City Beach, Fla.
  Sponsored by Robert Siragusa, MD, FAAD

HAWAII

- Island Pacific Academy, Kapolei, Hawaii
  Sponsored by Alex Carcamo, MD, FAAD

ILLINOIS

- Gus and Flora Kerasotes YMCA, Springfield, Ill.
  Sponsored by Stephen Stone, MD, FAAD

MISSOURI

- Hannibal Regional Hospital, Hannibal, Mo.
  Sponsored by Linda Cooke, MD, FAAD

NEW JERSEY

- Seth Boyden Elementary Demonstration School, Maplewood, N.J.
  Sponsored by Michael Ehrenreich, MD, FAAD

PENNSYLVANIA

- City of Bethlehem Health Bureau, Bethlehem, Pa.
  Sponsored by David Vasily, MD, FAAD

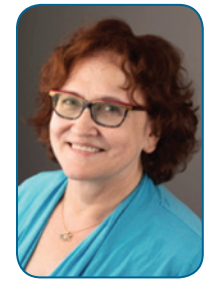
TEXAS

- Wilma Fisher Elementary Parent Teacher Association, Frisco, Texas
  Sponsored by Lucy Li, MD, FAAD
- Oak Hill Elementary PTA, Austin, Texas
  Sponsored by Mary Ann Martinez, MD, FAAD
- Holy Cross Christian Academy, Burleson, Texas
  Sponsored by Angela Shedd, MD, FAAD
- Armed Services YMCA El Paso, El Paso, Texas
  Sponsored by Brett Ozanich, MD, FAAD

AAD member dermatologists play an integral role in the program by encouraging local organizations to apply for the grants and by writing letters of support, a requirement for consideration of applications. The program is open to nonprofit organizations that serve children and teens under the age of 18 and have incorporated a sun safety program into their activities for at least one year. Grants are available for permanent shade structures over outdoor locations that are not protected from the sun, such as playgrounds, pools and eating areas.

For organizations interested in offering a sun safety program, the AAD has developed a curriculum for 8 to 13 year-olds to promote healthy self-esteem through education about skin, hair and nails. The Good Skin Knowledge lesson plans and accompanying activities include sun safety education, which meets the Shade Structure Grant Program's sun safety requirement when in place for one year prior to application.

The AAD's Shade Structure Grant Program is financially supported by the AAD and its members' contributions. This program is part of the AAD's SPOT Skin Cancer™ campaign to create a world without skin cancer through public awareness, community outreach programs and services, and advocacy that promote the prevention, detection and care of skin cancer.



Suzanne M. Olbricht, MD, FAAD, a Boston-based dermatologist, is currently the President of the AAD. Dr. Olbricht is an associate professor of dermatology at Harvard Medical School and chief of dermatology at Beth Israel Deaconess Medical Center in Boston. She previously served the AAD as Secretary-Treasurer, Assistant Secretary-Treasurer and a member of its Board of Directors. She has also served as chair of the AAD's Scientific Assembly Committee. Dr. Olbricht is a past president of the New England Dermatology Society.

JDPA Journal of Dermatology for Physician Assistants

INFORMATION FOR AUTHORS – The JDPA is a peer-reviewed publication that delivers innovative clinical, surgical, cosmetic, and professional content exclusively for dermatology PAs. Submissions to the JDPA are peer-reviewed by a panel of experienced dermatology PAs, educational PAs, and dermatologists before articles are accepted for publication.

Manuscripts submitted for publication will be reviewed with the understanding that they are original and have not been submitted elsewhere nor are being considered by other journals. Electronic submissions are accepted and should be sent to editor@jdpa.org.

The five main sections featured in each issue of the JDPA are listed below along with a brief description of the various topics that authors can contribute to. Regardless of the section, all articles must follow the following criteria:

- ***Formatting*** - Times New Roman font, 12 point, double-spaced, left aligned.
- ***Article Order*** - Title, Author(s), Author bios (including disclosures), Text of Article, References, Tables, and Figures
- ***Reference Citations*** - Utilize the AMA Manual of Style, 10th Edition.

DERMATOLOGY PA NEWS AND NOTES

Feature Articles

Write a review about a new or innovative dermatological procedure, device, and/or approach to patient care (500-1000 words).

From The Desk Of…

Write an opinion essay sharing your insight regarding a current "hot item" issue *(e.g., specialty PA credentialing, dermatology access to care, supervising physician relationships, etc.)* or any other topic regarding the field of dermatology (250-1000 words).

CLINICAL DERMATOLOGY

CME articles

Content should be specific to the field of dermatology following any of the following formats:

Study – Original research (clinical or basic science).
Professional issues or health policy papers.
Review – Scholarly review of a topic.

Content length:

6 pages (requires 4 self-assessment Q&A) = .5hr of Cat. I CME.
12 pages (requires 8 self-assessment Q&A) = 1hr of Cat. I CME.

Article should include written learning objectives (3-4 required).

Dermatology Case Report

Write a report and discuss a case(s) that illustrate an important or interesting observation (500-1500 words).

Journal Club: Dermatology PA Perspectives

Write a review of an already published article from an established dermatology journal *(e.g., JAAD, Cos Dermatol, Dermatol Surg, etc.),* summarizing the practical thoughts and clinical issues (250-1000 words).

From the Patient's Perspective

Patients' stories published in their own words. JDPA staff can even assist patients with writing their stories (250-1000 words).

Clinical Snapshots

Write a brief written description and clinical facts about an interesting cutaneous anomaly (250-500 words).

Drugs in Dermatology

Write about the current information regarding a particular dermatological medication, drug interaction, or medication side effect/adverse reaction (250-1000 words).

Dermatology Evidence-Based Medicine (derm EBM)

Write a brief, evidence-based assessment of the one or two most relevant studies retrieved to answer a focused clinical question that may have arisen from a real-life situation. A derm EBM is not a comprehensive review of a subject or a synthesis of all the available knowledge (500–1500 words).

SURGICAL DERMATOLOGY

Feature Articles

Write a review about a new or innovative surgical procedure, device, and/or approach to patient care (500-1000 words).

Surgical Wisdom

Write a brief article on a fact or pearl for the surgical setting (250-500 words).

Surgical Dermatology Case Report

Write a report and discuss a case(s) that illustrate an important or interesting observation (500-1500 words).

Journal Club: Dermatology PA Perspectives

Write a review of an already published article from an established dermatology journal *(e.g., JAAD, Cos Dermatol, Dermatol Surg, etc.),* summarizing the practical thoughts and clinical issues (250-1000 words).

COSMETIC DERMATOLOGY

Feature Articles

Write a review about a new or innovative cosmetic procedure, device, and/or approach to patient care (500-1000 words).

Cosmetic Pearls

Write a brief article on a fact or pearl for the cosmetic setting (250-500 words).

Cosmetic Dermatology Case Report

Write a report and discuss a case(s) that illustrate an important or interesting observation (500-1500 words).

Journal Club: Dermatology PA Perspectives

Write a review of an already published article from an established dermatology journal *(e.g., JAAD, Cos Dermatol, Dermatol Surg, etc.),* summarizing the practical thoughts and clinical issues (250-1000 words).

PROFESSIONAL DEVELOPMENT

Feature Articles

Write an article that explores the professional issues dermatology PAs face such as reimbursement, education, medical trends, contracts, office management, etc. (500-1500 words).

Outside & Inside the 9 to 5

Allow us to share your story of the good work that you do either outside or inside your practice of dermatology. You can write this article yourself or the JDPA staff can interview you to write the article (250-1000 words). **Notes From Your Office Manager**
Write a brief article on a fact or pearl for the office setting (250-500 words).

Judicial and Ethical Affairs

Write an article that explores the complex or multifaceted ethical or judicial professional issues that affect the practice of dermatology for PAs (250-1000 words).

To read the JDPA publication's Ethics and Malpractice Statement, please visit www.jdpa.org/write.html.

ADVERTISER INDEX

For more information on advertising opportunities in the JDPA, please log on to www.jdpa.org

BRIEF SUMMARY OF FULL PRESCRIBING INFORMATION

This Brief Summary does not include all the information needed to use ONEXTON Gel safely and effectively. See full prescribing information for ONEXTON Gel.

ONEXTON™ (clindamycin phosphate and benzoyl peroxide) Gel, 1.2%/3.75%, for topical use

Initial U.S. Approval: 2000

CONTRAINDICATIONS

Hypersensitivity

ONEXTON Gel is contraindicated in those individuals who have shown hypersensitivity to clindamycin, benzoyl peroxide, any components of the formulation, or lincomycin. Anaphylaxis, as well as allergic reactions leading to hospitalization, has been reported in postmarketing use with ONEXTON Gel [see Adverse Reactions]

WARNINGS AND PRECAUTIONS

Colitis

Systemic absorption of clindamycin has been demonstrated following topical use of clindamycin. Diarrhea, bloody diarrhea, and colitis (including pseudomembranous colitis) have been reported with the use of topical and systemic clindamycin. If significant diarrhea occurs, ONEXTON Gel should be discontinued.

Severe colitis has occurred following oral and parenteral administration of clindamycin with an onset of up to several weeks following cessation of therapy. Antiperistaltic agents such as opiates and diphenoxylate with atropine may prolong and/or worsen severe colitis. Severe colitis may result in death.

Studies indicate toxin(s) produced by Clostridia is one primary cause of antibiotic-associated colitis. The colitis is usually characterized by severe persistent diarrhea and severe abdominal cramps and may be associated with the passage of blood and mucus. Stool cultures for Clostridium difficile and stool assay for C. difficile toxin may be helpful diagnostically.

Ultraviolet Light and Environmental Exposure

Minimize sun exposure (including use of tanning beds or sun lamps) following drug application [see Nonclinical Toxicology].

ADVERSE REACTIONS

The following adverse reaction is described in more detail in the Warnings and Precautions section of the label:

Colitis [see Warnings and Precautions].

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in clinical trials of a drug cannot be directly compared to rates observed in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

These adverse reactions occurred in less than 0.5% of subjects treated with ONEXTON Gel: burning sensation (0.4%); contact dermatitis (0.4%); pruritus (0.4%); and rash (0.4%).

During the clinical trial, subjects were assessed for local cutaneous signs and symptoms of erythema, scaling, itching, burning and stinging. Most local skin reactions either were the same as baseline or increased and peaked around week 4 and were near or improved from baseline levels by week 12. The percentage of subjects that had symptoms present before treatment (at baseline), during treatment, and the percent with symptoms present at week 12 are shown in Table 1.

Table 1: Local Skin Reactions - Percent of Subjects with Symptoms Present. Results from the Phase 3 Trial of ONEXTON Gel 1.2%/3.75% (N = 243)

	Before Treatment (Baseline)			Maximum During Treatment			End of Treatment (Week 12)		
	Mild	Mod.*	Severe	Mild	Mod.*	Severe	Mild	Mod.*	Severe
Erythema	20	6	0	28	5	<1	15	2	0
Scaling	10	1	0	19	3	0	10	<1	0
Itching	14	3	<1	15	3	0	7	2	0
Burning	5	<1	<1	7	1	<1	3	<1	0
Stinging	5	<1	0	7	0	<1	3	0	<1

*Mod. = Moderate

Postmarketing Experience

Because postmarketing adverse reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Anaphylaxis, as well as allergic reactions leading to hospitalizations, has been reported in postmarketing use of products containing clindamycin phosphate/benzoyl peroxide.

DRUG INTERACTIONS

Erythromycin

Avoid using ONEXTON Gel in combination with topical or oral erythromycin-containing products due to its clindamycin component. In vitro studies have shown antagonism between erythromycin and clindamycin. The clinical significance of this in vitro antagonism is not known.

Concomitant Topical Medications

Concomitant topical acne therapy should be used with caution since a possible cumulative irritancy effect may occur, especially with the use of peeling, desquamating, or abrasive agents. If irritancy or dermatitis occurs, reduce frequency of application or temporarily interrupt treatment and resume once the irritation subsides. Treatment should be discontinued if the irritation persists.

Neuromuscular Blocking Agents

Clindamycin has been shown to have neuromuscular blocking properties that may enhance the action of other neuromuscular blocking agents. ONEXTON Gel should be used with caution in patients receiving such agents.

USE IN SPECIFIC POPULATIONS

Pregnancy

Pregnancy Category C.

There are no adequate and well-controlled studies in pregnant women treated with ONEXTON Gel. ONEXTON Gel should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Animal reproductive/developmental toxicity studies have not been conducted with ONEXTON Gel or benzoyl peroxide. Developmental toxicity studies of clindamycin performed in rats and mice using oral doses of up to 600 mg/kg/day (240 and 120 times amount of clindamycin in the highest recommended adult human dose based on mg/m^2, respectively) or subcutaneous doses of up to 200 mg/kg/day (80 and 40 times the amount of clindamycin in the highest recommended adult human dose based on mg/m^2, respectively) revealed no evidence of teratogenicity.

Nursing Mothers

It is not known whether clindamycin is excreted in human milk after topical application of ONEXTON Gel. However, orally and parenterally administered clindamycin has been reported to appear in breast milk. Because of the potential for serious adverse reactions in nursing infants, a decision should be made whether to use ONEXTON Gel while nursing, taking into account the importance of the drug to the mother.

Pediatric Use

Safety and effectiveness of ONEXTON Gel in pediatric patients under the age of 12 have not been evaluated.

Geriatric Use

Clinical trials of ONEXTON Gel did not include sufficient numbers of subjects aged 65 and older to determine whether they respond differently from younger subjects.

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenicity, mutagenicity and impairment of fertility testing of ONEXTON Gel have not been performed.

Benzoyl peroxide has been shown to be a tumor promoter and progression agent in a number of animal studies. Benzoyl peroxide in acetone at doses of 5 and 10 mg administered topically twice per week for 20 weeks induced skin tumors in transgenic Tg.AC mice. The clinical significance of this is unknown.

Carcinogenicity studies have been conducted with a gel formulation containing 1% clindamycin and 5% benzoyl peroxide. In a 2-year dermal carcinogenicity study in mice, treatment with the gel formulation at doses of 900, 2700, and 15000 mg/kg/day (1.8, 5.4, and 30 times amount of clindamycin and 2.4, 7.2, and 40 times amount of benzoyl peroxide in the highest recommended adult human dose of 2.5 g ONEXTON Gel based on mg/m^2, respectively) did not cause any increase in tumors. However, topical treatment with a different gel formulation containing 1% clindamycin and 5% benzoyl peroxide at doses of 100, 500, and 2000 mg/kg/day caused a dose-dependent increase in the incidence of keratoacanthoma at the treated skin site of male rats in a 2-year dermal carcinogenicity study in rats. In an oral (gavage) carcinogenicity study in rats, treatment with the gel formulation at doses of 300, 900 and 3000 mg/kg/day (1.2, 3.6, and 12 times amount of clindamycin and 1.6, 4.8, and 16 times amount of benzoyl peroxide in the highest recommended adult human dose of 2.5 g ONEXTON Gel based on mg/m^2, respectively) for up to 97 weeks did not cause any increase in tumors. In a 52-week dermal photocarcinogenicity study in hairless mice, (40 weeks of treatment followed by 12 weeks of observation), the median time to onset of skin tumor formation decreased and the number of tumors per mouse increased relative to controls following chronic concurrent topical administration of the higher concentration benzoyl peroxide formulation (5000 and 10000 mg/kg/day, 5 days/week) and exposure to ultraviolet radiation.

Clindamycin phosphate was not genotoxic in the human lymphocyte chromosome aberration assay. Benzoyl peroxide has been found to cause DNA strand breaks in a variety of mammalian cell types, to be mutagenic in *S. typhimurium* tests by some but not all investigators, and to cause sister chromatid exchanges in Chinese hamster ovary cells.

Fertility studies have not been performed with ONEXTON Gel or benzoyl peroxide, but fertility and mating ability have been studied with clindamycin. Fertility studies in rats treated orally with up to 300 mg/kg/day of clindamycin (approximately 120 times the amount of clindamycin in the highest recommended adult human dose of 2.5 g ONEXTON Gel, based on mg/m^2) revealed no effects on fertility or mating ability.

PATIENT COUNSELING INFORMATION

See FDA-approved patient labeling (Patient Information).

Manufactured for:
Valeant Pharmaceuticals North America LLC
Bridgewater, NJ 08807 USA
By:
Valeant Pharmaceuticals International, Inc.
Laval, Quebec H7L 4A8, Canada
U.S. Patent 8,288,434

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Ortho | Dermatologics

ALL ABOARD ONEXTON GEL

Efficacy and tolerability matter when it comes to treating acne. In the pivotal trial, ONEXTON GEL was shown to treat both inflammatory and noninflammatory acne, and no patients discontinued due to an adverse event.[1,2]

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TERMS AND CONDITIONS APPLY

INDICATION

ONEXTON (clindamycin phosphate and benzoyl peroxide) Gel, 1.2%/3.75% is indicated for the topical treatment of acne vulgaris in patients 12 years of age or older.

IMPORTANT SAFETY INFORMATION

- ONEXTON Gel is contraindicated in patients with a known hypersensitivity to clindamycin, benzoyl peroxide, any component of the formulation, or lincomycin.
- ONEXTON Gel is contraindicated in patients with a history of regional enteritis, ulcerative colitis, or antibiotic-associated colitis.
- Diarrhea, bloody diarrhea, and colitis (including pseudomembranous colitis) have been reported with the use of topical and systemic clindamycin. ONEXTON Gel should be discontinued if significant diarrhea occurs.
- Orally and parenterally administered clindamycin has been associated with severe colitis, which may result in death.
- Anaphylaxis, as well as other allergic reactions leading to hospitalizations, has been reported in postmarketing use of products containing clindamycin/benzoyl peroxide. If a patient develops symptoms of an allergic reaction such as swelling and shortness of breath, they should be instructed to discontinue use and contact a physician immediately.
- The most common local adverse reactions experienced by patients in clinical trials were mild and moderate erythema, scaling, itching, burning and stinging.
- ONEXTON Gel should not be used in combination with erythromycin-containing products because of its clindamycin component.
- ONEXTON Gel should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. A decision should be made whether to use ONEXTON Gel while nursing, taking into account the importance of the drug to the mother.
- Patients should be advised to avoid contact with the eyes or mucous membranes.
- Patients should minimize exposure to natural and avoid artificial sunlight (tanning beds or UVA/B treatment) while using ONEXTON Gel. To minimize exposure to sunlight, protective clothing should be worn and a sunscreen with SPF 15 rating or higher should be used.

To report SUSPECTED ADVERSE REACTIONS, contact Ortho Dermatologics at 1-800-321-4576 or FDA at 1-800-FDA-1088 or visit www.fda.gov/medwatch.

Please see Brief Summary of full Prescribing Information on the following page.

References: 1. ONEXTON [prescribing information]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC. **2.** Pariser DM, Rich P, Cook-Bolden FE, Korotzer A. An aqueous gel fixed combination of clindamycin phosphate 1.2% and benzoyl peroxide 3.75% for the once-daily treatment of moderate to severe acne vulgaris. *J Drugs Dermatol*. 2014;13(9):1083-1089.

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ONEXTON®
(clindamycin phosphate and benzoyl peroxide)
Gel, 1.2%/3.75%