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JDPA

Journal of Dermatology for Physician Assistants

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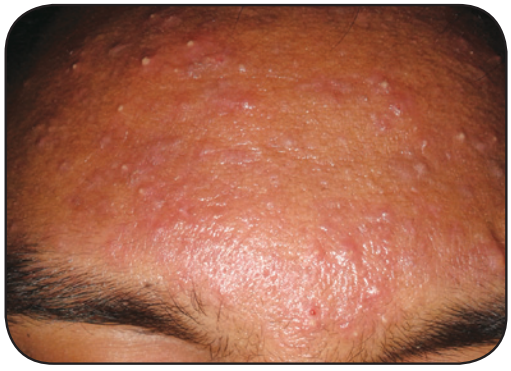

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CME

Depression Risk in the Treatment of Moderate to Severe Acne with Isotretinoin 18

Official Journal of the Society of Dermatology Physician Assistants

INDICATION

ALTRENO™ (tretinoin) lotion, 0.05% is indicated for the topical treatment of acne vulgaris in patients 9 years of age and older.

IMPORTANT SAFETY INFORMATION

ALTRENO is for topical use only. Not for ophthalmic, oral, or intravaginal use.

Skin Irritation: Patients using ALTRENO may experience application site dryness, pain, erythema, irritation, and exfoliation. Depending upon the severity of these adverse reactions, instruct patients to use a moisturizer, reduce the frequency of the application of ALTRENO, or discontinue use. Avoid application of ALTRENO to eczematous or sunburned skin.

Ultraviolet Light and Environmental Exposure: Minimize unprotected exposure to ultraviolet light, including sunlight and sunlamps. Warn patients with frequent sun exposure and those with inherent sensitivity to sunlight to exercise caution. Use sunscreen and protective clothing over treated areas when exposure cannot be avoided.

Fish Allergies: ALTRENO contains soluble fish proteins. Use with caution in patients with known sensitivity or allergy to fish. Advise patients to contact their healthcare provider if they develop pruritus or urticaria.

Adverse Reactions: The most common adverse reactions in clinical trials were application site dryness (4%), pain (3%), erythema (2%), irritation (1%) and exfoliation (1%).

Nursing Women: It is not known whether topical administration of tretinoin could result in sufficient systemic absorption to produce detectable concentrations in human milk. The developmental health benefits of breastfeeding should be considered along with the mother's clinical need for ALTRENO and any potential adverse effects on the breastfed child from ALTRENO.

To report SUSPECTED ADVERSE REACTIONS, contact Customer Service at 1-800-321-4576 or the FDA at 1-800-FDA-1088 or fda.gov/medwatch.

Please see Brief Summary of Prescribing Information on preceding pages.

References: 1. Altreno lotion [package insert]. Bridgewater, NJ: Ortho Dermatologics a division of Bausch Health Companies, Bridgewater, NJ 08807 USA. **2.** Data on file. Ortho Dermatologics a division of Bausch Health Companies, Bridgewater, NJ 08807 USA.

Altreno™
(tretinoin) Lotion, 0.05%

Ortho | Dermatologics

BRIEF SUMMARY OF PRESCRIBING INFORMATION

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

ALTRENO™ (tretinoin) lotion, for topical use
Initial U.S. Approval: 1973

INDICATIONS AND USAGE

ALTRENO™ (tretinoin) lotion, 0.05% is indicated for the topical treatment of acne vulgaris in patients 9 years of age and older.

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

Skin Irritation

Patients using ALTRENO may experience application site dryness, pain, erythema, irritation, and exfoliation. Depending upon the severity of these adverse reactions, instruct patients to use a moisturizer, reduce the frequency of the application of ALTRENO, or discontinue use. Avoid application of ALTRENO to eczematous or sunburned skin.

Ultraviolet Light and Environmental Exposure

Minimize unprotected exposure to ultraviolet light including sunlight and sunlamps during the use of ALTRENO. Warn patients who normally experience high levels of sun exposure and those with inherent sensitivity to sun to exercise caution. Use sunscreen products and protective clothing over treated areas when sun exposure cannot be avoided.

Fish Allergies

ALTRENO contains soluble fish proteins. Use with caution in patients with known sensitivity or allergy to fish. Advise patients to contact their healthcare provider if they develop pruritus or urticaria.

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 clinical practice.

In 2 randomized, double-blind, vehicle-controlled trials, subjects age 9 years and older applied ALTRENO or vehicle once daily for 12 weeks. The majority of subjects were White (74%) and female (55%). Approximately 47% were Hispanic/Latino and 45% were younger than 18 years of age. Adverse reactions reported by ≥1% of subjects treated with ALTRENO and more frequently than vehicle are summarized in Table 1.

Table 1: Adverse Reactions Reported by ≥1% of Subjects Treated with ALTRENO and More Frequently than Vehicle

Adverse Reactions n (%)		
	ALTRENO N=767	Vehicle N=783
Application site dryness	29 (4)	1 (<1)
Application site pain[1]	25 (3)	3 (<1)
Application site erythema	12 (2)	1 (<1)
Application site irritation	7 (1)	1 (<1)
Application site exfoliation	6 (1)	3 (<1)

[1]Application site pain defined as application site stinging, burning or pain.

Skin irritation was evaluated by active assessment of erythema, scaling, hypopigmentation, hyperpigmentation, itching, burning and stinging. The percentage of subjects who were assessed to have these signs and symptoms at any post baseline visit are summarized in Table 2.

Table 2: Application Site Tolerability Reactions at Any Post Baseline Visit

	ALTRENO N=760 Mild/Mod/Severe	Vehicle N=782 Mild/Mod/Severe
Erythema	51%	44%
Scaling	49%	30%
Hypopigmentation	12%	10%
Hyperpigmentation	35%	35%
Itching	35%	28%
Burning	30%	14%
Stinging	21%	8%

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

Available data from published observational studies of topical tretinoin in pregnant women have not established a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. There are no data on ALTRENO use in pregnant women. The systemic levels following topical administration are lower than with administration of oral tretinoin; however, absorption of this product may result in fetal exposure. There are reports of major birth defects similar to those seen in infants exposed to oral retinoids, but these case reports do not establish a pattern or association with tretinoin-related embryopathy *(see Data)*.

Animal reproduction studies have not been conducted with ALTRENO. Topical administration of tretinoin in a different formulation to pregnant rats during organogenesis was associated with malformations (craniofacial abnormalities [hydrocephaly], asymmetrical thyroids, variations in ossification, and increased supernumerary ribs) at doses up to 0.5 mg tretinoin/kg/day, approximately 2 times the maximum recommended human dose (MRHD) based on body surface area (BSA) comparison and assuming 100% absorption. Oral administration of tretinoin to pregnant cynomolgus monkeys during organogenesis was associated with malformations at 10 mg/kg/day (approximately 100 times the MRHD based on BSA comparison and assuming 100% absorption) *(see Data)*.

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of major birth defects, loss, and other adverse outcomes. The background risk in the U.S. general population of major birth defects is 2 to 4% and of miscarriage is 15 to 20% of clinically recognized pregnancies.

Data

Human Data

While available studies cannot definitively establish the absence of risk, published data from multiple prospective controlled observational studies on the use of topical tretinoin products during pregnancy have

not identified an association with topical tretinoin and major birth defects or miscarriage. The available studies have methodologic limitations, including small sample size and in some cases, lack of physical exam by an expert in birth defects. There are published case reports of infants exposed to topical tretinoin during the first trimester that describe major birth defects similar to those seen in infants exposed to oral retinoids; however, no pattern of malformations has been identified and no causal association has been established in these cases. The significance of these spontaneous reports in terms of risk to the fetus is not known.

Animal Data

Tretinoin in a 0.05% gel formulation was topically administered to pregnant rats during organogenesis at doses of 0.1, 0.3 and 1 g/kg/day (0.05, 0.15, 0.5 mg tretinoin/kg/day). Possible tretinoin malformations (craniofacial abnormalities [hydrocephaly], asymmetrical thyroids, variations in ossification, and increased supernumerary ribs) were observed at maternal doses of 0.5 mg tretinoin/kg/day (approximately 2 times the MRHD based on BSA comparison and assuming 100% absorption). These findings were not observed in control animals. Other maternal and reproductive parameters in tretinoin-treated animals were not different from control. For purposes of comparison of the animal exposure to human exposure, the MRHD is defined as 4 g of ALTRENO applied daily to a 60-kg person.

Other topical tretinoin embryofetal development studies have generated equivocal results. There is evidence for malformations (shortened or kinked tail) after topical administration of tretinoin to pregnant Wistar rats during organogenesis at doses greater than 1 mg/kg/day (approximately 5 times the MRHD based on BSA comparison and assuming 100% absorption). Anomalies (humerus: short 13%, bent 6%, os parietal incompletely ossified 14%) have also been reported when 10 mg/kg/day (approximately 50 times the MRHD based on BSA comparison and assuming 100% absorption) was topically applied to pregnant rats during organogenesis. Supernumerary ribs have been a consistent finding in rat fetuses when pregnant rats were treated topically or orally with retinoids.

Oral administration of tretinoin during organogenesis has been shown to induce malformations in rats, mice, rabbits, hamsters, and nonhuman primates. Fetal malformations were observed when tretinoin was orally administered to pregnant Wistar rats during organogenesis at doses greater than 1 mg/kg/day (approximately 5 times the MRHD based on BSA comparison). In the cynomolgus monkey, fetal malformations were reported when an oral dose of 10 mg/kg/day was administered to pregnant monkeys during organogenesis (approximately 100 times the MRHD based on BSA comparison). No fetal malformations were observed at an oral dose of 5 mg/kg/day (approximately 50 times the MRHD based on BSA comparison). Increased skeletal variations were observed at all doses in this study and dose-related increases in embryo lethality and abortion were reported in this study. Similar results have also been reported in pigtail macaques.

Oral tretinoin has been shown to be fetotoxic in rats when administered at doses 10 times the MRHD based on BSA comparison. Topical tretinoin has been shown to be fetotoxic in rabbits when administered at doses 4 times the MRHD based on BSA comparison.

Lactation

Risk Summary

There are no data on the presence of tretinoin or its metabolites in human milk, the effects on the breastfed infant, or the effects on milk production. It is not known whether topical administration of tretinoin could result in sufficient systemic absorption to produce detectable concentrations in human milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for ALTRENO and any potential adverse effects on the breastfed child from ALTRENO.

Pediatric Use

Safety and effectiveness of ALTRENO for the topical treatment of acne vulgaris have been established in pediatric patients age 9 years to less than 17 years based on evidence from two multicenter, randomized, double-blind, parallel-group, vehicle-controlled, 12-week trials and an open-label pharmacokinetic study. A total of 318 pediatric subjects aged 9 to less than 17 years received ALTRENO in the clinical studies [see *Clinical Pharmacology* and *Clinical Studies* in full Prescribing Information].

The safety and effectiveness of ALTRENO in pediatric patients below the age of 9 years have not been established.

Geriatric Use

Clinical trials of ALTRENO did not include any subjects age 65 years and older to determine whether they respond differently from younger subjects.

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility

A 2-year dermal mouse carcinogenicity study was conducted with topical administration of 0.005%, 0.025% and 0.05% of a tretinoin gel formulation. Although no drug-related tumors were observed in surviving animals, the irritating nature of the drug product precluded daily dosing, confounding data interpretation and reducing the biological significance of these results.

Studies in hairless albino mice with a different formulation suggest that concurrent exposure to tretinoin may enhance the tumorigenic potential of carcinogenic doses of UVB and UVA light from a solar simulator. This effect was confirmed in a later study in pigmented mice, and dark pigmentation did not overcome the enhancement of photocarcinogenesis by 0.05% tretinoin. Although the significance of these studies to humans is not clear, patients should minimize exposure to sunlight or artificial ultraviolet irradiation sources.

The genotoxic potential of tretinoin was evaluated in an in vitro bacterial reversion test, an in vitro chromosomal aberration assay in human lymphocytes and an in vivo rat micronucleus assay. All tests were negative.

In dermal fertility studies of another tretinoin formulation in rats, slight (not statistically significant) decreases in sperm count and motility were seen at 0.5 mg/kg/day (approximately 2 times the MRHD based on BSA comparison and assuming 100% absorption), and slight (not statistically significant) increases in the number and percent of nonviable embryos in females treated with 0.25 mg/kg/day and above (approximately the MRHD based on BSA comparison and assuming 100% absorption) were observed.

PATIENT COUNSELING INFORMATION

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

Distributed by:
Ortho Dermatologics, a division of Bausch Health US, LLC.
Bridgewater, NJ 08807 USA

U.S. Patent Number: 6,517,847

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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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EDITOR'S **MESSAGE**

Summer is finally here! For many of us the last day of school marks the beginning of summer vacation for our children. This often means time for fun trips and quality family time. In regards to our office routines, summer often means a bump up in the number of pediatric patients on our daily schedule. Often, parents wait until summer to get their children in to be seen if it is not urgent in nature. Summer appointments mean children don't have to miss out on precious class time. As we all know, time is such a precious commodity.

Time is important to us as providers and it is certainly valued by our patients as well. In this issue's Outside & Inside the 9 to 5… we are sharing with you an abbreviated version of a project that the SDPA leadership has been working on regarding patient wait time. Now more than ever it is so important that we educate others on the vital role that we play as dermatology PAs in helping to address the wait time crisis. We as PAs are so important in providing patients with access to quality dermatological care when our supervising physicians are booking out months at a time. The SDPA teamed up with the Greater Access for Patients Partnership (GAPP) to create an extensive summary of what wait time does to our patient population as well as what we as dermatology PAs are doing to aid in this crisis. The complete project can be found on the SDPA webpage at www.dermpa.org. I encourage you to take a look at it in its entirety and share it with your supervising physician, office staff, and patients alike.

We all value our time and if we can help alleviate the extensive wait time crisis in dermatology for our patients then mission accomplished. A big thumbs up to the SDPA leadership for once again paying attention to the needs of our patients and looking for ways to continue to improve and better their experiences when obtaining care from us. I hope everyone is able to enjoy a little extra time and some summer fun in the days ahead.

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

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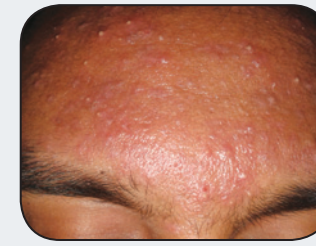
By Joleen M. Volz, DMSc, PA-C, DFAAPA



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This program is not yet approved for CME Credit. Conference organizers plan to request maximum of 25 hours (21maximum earnable by any attendee) of Category I CME Credit from AAPA.

We look forward to seeing you in Atlanta!

CALENDAR OF EVENTS

2019

JULY
AAD Summer Meeting
July 25 – 28, 2019
New York, NY

NOVEMBER
SDPA 17th Annual Fall Dermatology Conference
November 21 – 24, 2019
The Westin Kierland Resort & Spa
Scottsdale, AZ

2020

MAY
SDPA Annual Summer Dermatology Conference
May 13 – 17, 2020
Hyatt Regency Denver at Colorado Convention Center
Denver, CO

AUGUST
AAD Summer Meeting
August 13 –16, 2020
Seattle, Washington

OCTOBER
SDPA Annual Fall Dermatology Conference
October 29 – November 1, 2020
InterConinental Miami
Miami, Florida

Empower. Educate. Advance.
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FROM THE SDPA
NEWS & CURRENT AFFAIRS

Dear Colleagues,

My time as President of the greatest specialty PA society has come to an end. It seems so long ago that I began this journey. As I reflect about the past year, I am honored, humbled and – in hindsight - *overwhelmed* to have had the opportunity to lead the SDPA. The year wasn't without its challenges; however, the rewards have exceeded any setbacks. It has been incredibly rewarding to lead alongside such amazing individuals who are all so supportive of each other and the Society.

My foray into leadership began through my service as a Committee Chair. I then advanced to the Board of Directors and ended up serving in the Secretary/Treasurer role. Other leaders began to ask, "When are you going to run for President?" At the time, I had responded that I was not interested, as I did not feel qualified. I'm happy to say that I eventually decided I would take on this responsibility. With great mentors around us we can do most anything.

I have watched leaders come and leaders go. What I most enjoy is watching leaders grow. Often, we assume others will take on the positions and we shy away. When we do step into a leadership position, it is often without any actual experience or understanding of expectations, and I recognize this can be intimidating.

As I grew in leadership with the SDPA, I also grew as a leader in my clinical practice and as a person. Somewhere along the way, I decided to further my education during this process to a terminal degree, Doctor of Medical Science. I would not advise taking this on at the same time of a busy presidential year! Below are a few items that standout for me:

- It is evident that dermatology PAs are often scrutinized by our dermatologist colleagues as well as in the media. During the year we have worked alongside a PR firm to help promote dermatology PAs to the public in a positive image. The **GAPP (Greater Access for Patients Partnership)** has spread awareness to patient wait times and how PAs can effectively reduce wait times and increase patient quality care.
- Early on during the leadership year, the SDPA BOD decided to transition management from a corporate-owned management company to our own stand-alone nonprofit organization. This was a time of learning how to start a business on our own. We hired our own staff and secured an office in Alexandria, VA.

Again, it has been an honor serving as your SDPA President. I have very much enjoyed getting to meet dermatology PAs from all over the country and engaging in discussions about the challenges and the joys we face together. Giving back is more important than ever. Whether it's volunteering a few hours a month on a committee, donating to the DPAF or to the AAPA PAC, it is these acts that will propel our profession forward. Now is not the time to become apathetic. Take this moment to get involved! Contribute your talents to ensure our profession continues to thrive as the one we all love, and of which we are all so proud.

Respectfully Yours,

Joleen M. Volz

Joleen M. Volz, MPAS, PA-C, DFAAPA
SDPA President and Diplomate

Dermatology Market Watch

Ortho Dermatologics Announces Launch of Duobriitm (Halobetasol Propionate and Tazarotene) Lotion 0.01%/0.045% for Plaque Psoriasis in Adults

Ortho Dermatologics recently announced that DUOBRIITM (halobetasol propionate and tazarotene) Lotion, 0.01%/0.045%, is now available commercially to health care professionals in the U.S.. Approved by the U.S. Food and Drug Administration on April 25, 2019, DUOBRII is the first and only topical lotion that contains a unique combination of halobetasol propionate and tazarotene in one formulation.

When used separately to treat plaque psoriasis, the duration of use of halobetasol propionate is limited by FDA labeling constraints to two to four weeks duration and the use of tazarotene can be limited due to tolerability concerns. By combining halobetasol propionate and tazarotene in a patented once-daily moisturizing lotion, the DUOBRII formulation ensures uniform distribution, allowing for simultaneous contact with the skin surface. In a year-long safety study, patients used DUOBRII for up to 24 weeks of continuous use and up to 52 weeks of as-needed use. Unlike other topical products that either contain steroids or are steroids on their own, DUOBRII is not restricted to eight weeks or less of use. The approved labeling for DUOBRII does not include a duration limitation; it can be dosed to clearance as long as local skin reactions do not occur, and treatment should be discontinued once clearance is achieved.

DUOBRII Lotion is priced at $825 for a supply of a 100-gram tube, which is more than 50 percent lower than other branded topical combination products. Additionally, through the company's access program, most eligible, commercially insured patients will have a co-pay as little as $25.

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 study compares the effectiveness of a new medication for treatment of post-traumatic stress disorder with the standard treatment. Subjects with post-traumatic stress disorder are sorted with equal likelihood of selection to receive the new medication or the standard treatment. Neither the subjects themselves nor the clinicians know the treatment condition for each patient. Which of the following best describes this type of study?

A. Double-blind randomized cohort study
B. Randomized controlled trial with crossover design
C. Double-blind randomized clinical trial with crossover design
D. Double-blind randomized clinical trial
E. Double-blind quasi-experimental trial

EXPLANATION: In a double-blind randomized clinical trial neither the subjects, who are randomized to experiment group of control group; nor the researcher, who has contact with the subjects, knows if the subjects are in the treatment or control group. In a cohort study a population who has been exposed to a risk factor is identified and followed over time and compared to a population not exposed to the risk factor. Cohort studies are typically used for more common diseases. In a crossover study each group functions as the intervention and control, but at different times. In a double-blind randomized control trail with crossover design the study would have components of both the randomized trial and crossover study. A quasi-experimental trail is an interventional study that is used to estimate the impact of an intervention on a population without random assignment to treatment of control group. This question is an example of what may appear on the exam related to professional practice. Would encourage the reader to go to the NCCPA website to review the new updated exam blueprint.

The correct answer is D.

James A. Van Rhee, MS, PA-C, *is the Program Director for the Yale University School of Medicine Physician Assistant Online 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). He is the author of the Physician Assistant: Certification and Re-certification Review Book and Consulting Editor of Physician Assistant Clinics, both published by Elsevier. For the last fifteen years he has been course director and presenter of the Physician Assistant Board Review, produced live online by Kaplan Medical.*

Once-daily

Seysara®

(sarecycline) tablets

INTRODUCING SEYSARA, A NOVEL ORAL TETRACYCLINE DEVELOPED SPECIFICALLY FOR MODERATE TO SEVERE ACNE PATIENTS AS YOUNG AS 9.[1]

For more information, visit SEYSARA.com

***STUDY DESIGN:** The safety and efficacy of SEYSARA was assessed in two identically designed, 12-week, multicenter, randomized, double-blind, placebo-controlled trials. In both studies, SEYSARA was administered orally once-daily for 12 weeks as 60 mg, 100 mg, or 150 mg tablets, based on patient weight.

***STUDY RESULTS:** Mean absolute reduction (co-primary endpoint) was 15.3 in study 1 (SC1401) and 15.5 in study 2 (SC1402) vs 10.2 and 11.1 in the placebo groups at Week 12, respectively. 21.9% of ITT patients in study 1 and 22.6% of ITT patients in study 2 achieved IGA success (co-primary endpoint; defined as ≥2-point improvement from baseline in IGA scale for inflammatory lesions of acne, and a score of 0 [clear] or 1 [almost clear]) at Week 12 vs 10.5% and 15.3% of patients with placebo, respectively (p<.0001 for study 1 and p=.0038 for study 2).

INDICATIONS AND USAGE

SEYSARA (sarecycline) tablet, is indicated for the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 9 years of age and older.

Limitations of Use: Efficacy of SEYSARA beyond 12 weeks and safety beyond 12 months have not been established. SEYSARA 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, SEYSARA should be used only as indicated.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS

- The use of SEYSARA during **tooth development** (second and third trimesters of pregnancy, infancy, and childhood up to the age of 8 years) may cause permanent discoloration of the teeth (yellow-gray-brown).
- ***Clostridium difficile* associated diarrhea (CDAD)** has been reported with nearly all antibacterial agents, and may range in severity from mild diarrhea to fatal colitis. If *Clostridium difficile* Associated Diarrhea (antibiotic associated colitis) occurs, discontinue SEYSARA.

WHAT DO I SAY TO PATIENTS FRUSTRATED WITH ACNE?

I SEYSARA®

TOUGH ON ACNE.

- Significant inflammatory lesion count reduction at Week 12, and as early as Week 3[1,*]

EASY ON PATIENTS.

- Convenient once-daily dosing, with 3 weight-based strengths; with or without food[1]

— With a demonstrated safety profile[1] —

- **Central nervous system side effects,** including light-headedness, dizziness or vertigo, have been reported with tetracycline use. Patients who experience these symptoms should be cautioned about driving vehicles or using hazardous machinery. These symptoms may disappear during therapy and may disappear when the drug is discontinued.
- **Intracranial hypertension** in adults and adolescents has been associated with the use of tetracyclines. Clinical manifestations include headache, blurred vision and papilledema. Although signs and symptoms of intracranial hypertension resolve after discontinuation of treatment, the possibility for sequelae such as visual loss that may be permanent or severe exists. Concomitant use of isotretinoin and SEYSARA should be avoided because isotretinoin, a systemic retinoid, is also known to cause intracranial hypertension.
- **Photosensitivity** manifested by an exaggerated sunburn reaction has been observed in some individuals taking tetracyclines. Patients should minimize or avoid exposure to natural or artificial sunlight (tanning beds or UVA/B treatment) while using SEYSARA.
- **Bacterial resistance** to tetracyclines may develop in patients using SEYSARA. Because of the potential for drug-resistant bacteria to develop during the use of SEYSARA, it should only be used as indicated.
- As with other antibiotic preparations, use of SEYSARA may result in overgrowth of non-susceptible organisms, including fungi. If **superinfection** occurs, SEYSARA should be discontinued and appropriate therapy instituted.

ADVERSE REACTIONS

Most common adverse reaction (incidence ≥ 1%) is nausea.

PLEASE TURN THE PAGE FOR BRIEF SUMMARY OF FULL PRESCRIBING INFORMATION.

IGA, investigator's global assessment; reflects the investigator's overall general assessment of the quantity and quality of inflammatory lesions (range 0-4 with 0 being clear and 4 being severe).

ITT, intent-to-treat.

Reference:
1. SEYSARA [package insert]. Exton, PA: Almirall, LLC, 2018.

USSEY0311c 05-2019

almirall

BRIEF SUMMARY OF FULL PRESCRIBING INFORMATION FOR SEYSARA® (sarecycline)

This brief summary does not include all the information needed to use SEYSARA safely and effectively. See full Prescribing Information for SEYSARA (sarecycline) tablets for oral use.

INDICATIONS AND USAGE

SEYSARA® (sarecycline) tablet, is indicated for the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 9 years of age and older.

Limitations of Use: Efficacy of SEYSARA beyond 12 weeks and safety beyond 12 months have not been established. SEYSARA 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, SEYSARA should be used only as indicated *[see Warnings and Precautions]*.

CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS

Teratogenic Effects

- SEYSARA, like other tetracyclines, can cause fetal harm when administered to a pregnant woman. If SEYSARA is used during pregnancy or if the patient becomes pregnant while taking SEYSARA, the patient should be informed of the potential hazard to the fetus and treatment should be stopped immediately.
- The use of drugs of the tetracycline-class during tooth development (second and third trimesters 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 these drugs, but has been observed following repeated short-term courses. Enamel hypoplasia has also been reported.
- 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 with SEYSARA during pregnancy in association with maternal toxicity *[see Use in Specific Populations]*.

***Clostridium difficile* Associated Diarrhea (Antibiotic Associated Colitis)**

Clostridium difficile associated diarrhea (CDAD) has been reported with nearly all antibacterial agents, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to potential 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* should be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of *C. difficile*, and surgical evaluation should be instituted as clinically indicated.

Central Nervous System Effects

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

Intracranial Hypertension

Intracranial hypertension in adults and adolescents has been associated with the use of tetracyclines. Clinical manifestations include headache, blurred vision and papilledema. Although signs and symptoms of intracranial hypertension resolve after discontinuation of treatment, the possibility for sequelae such as visual loss that may be permanent or severe exists. Women of childbearing age who are overweight have a greater risk for developing intracranial hypertension. Patients should be questioned for visual disturbances prior to initiation of treatment with tetracyclines. Concomitant use of isotretinoin and SEYSARA should be avoided because isotretinoin, a systemic retinoid, is also known to cause intracranial hypertension *[see Drug Interactions]*. If visual disturbance occurs during treatment, patients should be checked for papilledema.

Photosensitivity

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

Development of Drug Resistant Bacteria

Bacterial resistance to tetracyclines may develop in patients using SEYSARA. Because of the potential for drug-resistant bacteria to develop during the use of SEYSARA, it should only be used as indicated.

Superinfection/Potential for Microbial Overgrowth

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

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.

A total of 1064 subjects and 1069 subjects with moderate to severe acne vulgaris were treated with SEYSARA and placebo, respectively, for 12 weeks in 3 controlled clinical trials. The only adverse drug reaction that was reported in at least 1% of subjects was nausea, SEYSARA (3.1%) versus placebo (2.0%).

The following additional adverse drug reactions occurred in less than 1% of female SEYSARA subjects: vulvovaginal mycotic infection (0.8%) and vulvovaginal candidiasis (0.6%).

DRUG INTERACTIONS

Effect of Other Drugs on SEYSARA

Oral Retinoids: Tetracyclines may cause increased intracranial pressure as do oral retinoids, including isotretinoin and acitretin *[see Warnings and Precautions]*. Avoid coadministration of SEYSARA with oral retinoids.

Antacids and Iron Preparations: Coadministration with antacids containing aluminum, calcium or magnesium, bismuth subsalicylate, and iron-containing preparations may impair absorption of SEYSARA, similar to other tetracyclines, which may decrease its efficacy. Separate dosing of SEYSARA from antacids containing aluminum, calcium or magnesium, bismuth subsalicylate, and iron-containing preparations.

Effect of SEYSARA on Other Drugs

Penicillin: Similar to other tetracyclines, SEYSARA may interfere with the bactericidal action of penicillin. Avoid coadministration of SEYSARA with penicillin.

Anticoagulants: Similar to other tetracyclines, SEYSARA may depress plasma prothrombin activity, which may increase the risk of bleeding in patients who are on anticoagulant therapy. Decrease anticoagulant dosage when coadministered with SEYSARA as appropriate.

P-Glycoprotein (P-gp) Substrates: Concomitant use of SEYSARA may increase concentrations of concomitantly administered P-gp substrates (e.g. digoxin). Monitor for toxicities of drugs that are P-gp substrates and may require dosage reduction when given concurrently with SEYSARA.

Oral Hormonal Contraceptives: There is no clinically significant effect of SEYSARA on the efficacy of oral contraceptives containing ethinyl estradiol and norethindrone acetate.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary: SEYSARA, like tetracycline class drugs, may cause fetal harm, permanent discoloration of teeth, and reversible inhibition of bone growth when administered during pregnancy *[see Warnings and Precautions and Use in Specific Populations]*. The limited available human data are not sufficient to inform a drug-associated risk for birth defects or miscarriage. Tetracyclines are known to cross the placental barrier; therefore, SEYSARA may be transmitted from the mother to the developing fetus. In animal reproduction studies, sarecycline induced skeletal malformations in fetuses when orally administered to pregnant rats during the period of organogenesis at a dose 1.4 times the maximum recommended human dose (MRHD) of 150 mg/day (based on AUC comparison). When dosing with sarecycline continued through the period of lactation, decreases in offspring survival, offspring body weight, and implantation sites and viable embryos in offspring females occurred at a dose 3 times the MRHD (based on AUC comparison). The potential risk to the fetus outweighs the potential benefit to the mother from SEYSARA use during pregnancy; therefore, pregnant patients should discontinue SEYSARA as soon as pregnancy is recognized.

All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. 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.

Lactation

Risk Summary: Tetracyclines are excreted in human milk. Because of the potential for serious adverse reactions on bone and tooth development in nursing infants from tetracycline-class antibiotics, advise a woman that breastfeeding is not recommended with SEYSARA therapy *[see Warnings and Precautions]*.

Females and Males of Reproductive Potential

Infertility: Avoid using SEYSARA in males who are attempting to conceive a child. In a fertility study in rats, sarecycline adversely affected spermatogenesis when orally administered to male rats at a dose 8 times the MRHD (based on AUC comparison).

Pediatric Use

The safety and effectiveness of SEYSARA have been established in pediatric patients 9 years of age and older for the treatment of moderate to severe inflammatory lesions of non-nodular acne vulgaris.

Safety and effectiveness of SEYSARA in pediatric patients below the age of 9 years 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 SEYSARA did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

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Depression Risk in the Treatment of Moderate to Severe Acne with Isotretinoin

By Joleen M. Volz, DMSc, PA-C, DFAAPA

ABSTRACT

Acne, also known as acne vulgaris, is the most common type of skin disease and can affect people of all ages.[1] It affects approximately 80% of the US population.[1,2] It is a chronic skin condition that results from overactive sebaceous oil glands at the base of the hair follicle.[3] Acne can be associated with non-inflamed open or closed comedones and/or inflammatory papules, pustules, cysts, nodules, and scarring.[3] Acne is most commonly found on the face but can involve other areas of the skin such as the chest, back and shoulders.[3] Since 1982, isotretinoin has been routinely utilized for the treatment of moderate to severe acne.[4,6] It remains the most effective treatment for moderate to severe acne despite much controversy over isotretinoin treatment and its possible association with depression and suicide.[5]

Isotretinoin has been well established in the efficacy of treating acne vulgaris. Treatment with isotretinoin has been associated with a controversial risk of depression and suicide.[1] A lack of evidence-based research to demonstrate the positive correlation of isotretinoin-related depression and suicide remains. Considering that isotretinoin is a vitamin A analog, there is plausible assumption of the correlation of mood disturbance.[1] Isotretinoin is a fat-soluble compound that crosses the blood brain barrier and affects areas of the brain that have been implicated in the development of depression. Chronically administering isotretinoin at a dose of 1-mg/kg has been shown to increase depression-related behavior in some studies involving mice and rats, but not consistently in other studies.[1,6,7]

Keywords: *Isotretinoin, Accutane, Depression, Acne, Suicide*

» 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.

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Learning Objectives:

1. *Describe the psychosocial complications of moderate to severe acne vulgaris.*
2. *Discuss the treatment of moderate to severe acne vulgaris and the pharmacodynamics/side effects of isotretinoin therapy.*
3. *Review the current understanding of the relationship between depression and isotretinoin therapy in the management of moderate to severe acne vulgaris.*

INTRODUCTION

Acne, also known as acne vulgaris, affects people of all ages.[1] It is the most prevalent skin disease, affecting approximately 80% of the US population and nearly all adolescents to varying degrees.[1] The most common reason for a dermatologist referral is associated with acne.[1,7,8] Acne is a chronic skin condition that results from overactive sebaceous oil glands at the base of the hair follicle. It can be associated with non-inflamed open or closed comedones and/or inflammatory papules, pustules, cysts, nodules, and scarring. Acne is most commonly found on the face but can involve other areas of the

skin such as the chest, back and shoulders.

Acne vulgaris can impact both emotional and social well-being.[1] Acne can be painful and leave behind lasting scars.[1] Skin and the psyche are linked.[9] Psychologically the internal factors and emotional suffering can present, since the skin is so visible.[9] The appearance of skin is important in social interaction and self-image, especially throughout adolescence.[10] Mood disorders such as depression have been reported in patients that are affected by acne and other chronic illnesses.[8] It has been shown that acne has a greater effect on a person's mood than other chronic skin disorders including psoriasis, and alopecia.[1] Acne causes shyness and social isolation and it is often associated with anxiety and depression. Suicidal ideation, attempted suicide and body dysmorphia can be associated with a diagnosis of acne.[1] Acne can often affect a person's quality of life which is often underestimated. Acne has been considered as having similar quality of life effects when compared with patients diagnosed with asthma, epilepsy, diabetes, back pain, or arthritis.[6] It is important to have knowledge of the psychosocial problems that correlate with acne to deliver optimal patient care in this patient population.[10] The increase risk of psychological side effects that may be associated with having severe acne and long-term effects of scarring should be a consideration in selecting treatment despite the controversy.[10,11]

TREATMENT

There are many treatment options currently available for acne. Since its approval in the United States in 1982, isotretinoin, 13-cis-retinoic acid, released under the name of Accutane, has been routinely utilized for the treatment of moderate to severe acne that is recalcitrant to topical and oral antibiotic treatment.[2,4] Isotretinoin is the only available treatment that treats all of the etiologic factors of acne. It reduces the size of the sebaceous gland and sebum secretion, reduces the growth of the bacteria implicated in acne, Propionibacterium acnes, as well as decreases inflammation and comedone formation.[6] Isotretinoin permanently clears at least half and up to 70% of the patients treated after one course of treatment.[6] An optimal course of treatment consists of 1 mg/kg/day with a maximum cumulative dose of 120 mg/kg over a 4 to 6 month period.[11] Isotretinoin is a known teratogenic medication, classified category X, and is contraindicated in pregnancy and for those seeking to become pregnant during or one month post treatment. It is associated with numerous side effects, most of which are predictable, such as dry mucous membranes, headache, alopecia, hypertriglyceridemia, and joint and muscle pain.[1,4,6] Isotretinoin remains the most effective treatment for moderate to severe acne despite the associated controversy over isotretinoin treatment and its possible association with depression and suicide.[1,3]

SIDE EFFECTS

From 1982 to May 2000, the FDA received a total of 431 reports of U.S. patients that have reported the possibility of isotretinoin and psychosocial complaints.[4] Of the 431 total reports, 37 reports included patients that had committed suicide associated with isotretinoin treatment and 110 patients that were hospitalized for depression, suicidal ideation or attempt.[1] There were 284 reports of patients who reported depression that did not require hospitalization.[1,4] These reports lead to a new label warning: "Accutane may cause depression, psychosis and, rarely, suicidal ideation, suicide attempts and suicide. Discontinuation of Accutane therapy may be insufficient; further evaluation may be necessary. No mechanism of action has been established for these events."[4] Two studies that evaluated the spontaneous reports submitted to the FDA found no or little increase in psychiatric disease including depression in suicide in comparison to the general population.[12]

PHARMACODYNAMICS

Isotretinoin is a retinoid, a derivative of vitamin A.[1,11] Following oral administration, it is converted to all-trans retinoic acid within the sebocytes, which then suppress gland activity.[11] It is biologically conceivable that isotretinoin could negatively affect mood.[1] It can cross the blood brain barrier and affect the hippocampus and orbitofrontal cortex, the area of the brain responsible for depression.[1] There is decreased activity in the orbitofrontal cortex of the brain shown on functional magnetic resonance imaging (MRI) studies of patients on

isotretinoin.[10,18] Isotretinoin causes elevations in the production of dopamine in the brain that can lead to the controversial adverse mood effects.[8]

PSYCHOSOCIAL IMPACT

Health care providers can be insensitive of the psychosocial implications of dermatologic disorders and lack empathy toward the emotional aspect their patients may experience.[2] It cannot be disputed that severe acne vulgaris potentiates severe psychosocial complications despite treatment.[13] Adolescence are at 3% to 11% increased risk for depression and suicide. Case reports, database studies, and retrospective studies show a potential association of isotretinoin and depression.[1] Large prospective studies, on the contrary, show no association with depression and sometimes show improvement of depression scores.[1,6] Rubinow et al, was one of the first to show improvement in psychosocial measures in patients treated with isotretinoin for cystic acne.[10] Another such study, Marron et al. concluded that improving a patient's acne with isotretinoin improved their mood.[2] This can be attributed to improving the patients self-esteem.[10] Halvorsen et al concludes the increase rate of reported suicidal ideation and mental health issues among adolescents that are candidates for isotretinoin, reflects the increased psychosocial issues as it relates to severe acne independent of therapy.[10,11] Studies that show the positive effects of isotretinoin on mood contribute it to acne related low self-esteem and subsequent poor quality of life prior to treatment.[8]

ISOTRETINOIN AND DEPRESSION

There have been nearly 500 case reports of depression out of the millions of patients that have been treated with isotretinoin.[14] There have been mixed results in multiple case series, controlled trials and population studies of isotretinoin showing a causal role in depression and suicide.[15] The majority of the evidence in support of the association between isotretinoin and depression have been from case reports and adverse event reporting to the FDA. The effects of isotretinoin may be dose dependent. Epidemiological studies have not shown an increased risk of depression or suicide with isotretinoin as compared with oral antibiotics for the treatment of acne.[10] In twelve controlled studies of greater than 800 patients, there was not an increased risk of anxiety, depression or attempted suicide.[11] Isotretinoin was associated with an improvement in anxiety and depression in nine of the aforementioned twelve controlled studies.[11]

In establishing a causal relationship between a drug and an adverse effect, it is necessary to show a temporal relationship between administration of the drug and the onset of adverse event.[16] Case reports with the strongest causal association indicate improvement of depression symptoms when isotretinoin is withdrawn and worsening of symptoms when the drug is reintroduced.[11]

There remains a lack of evidence-based research to demonstrate a positive correlation that isotretinoin causes depression, suicidal ideation, and suicide.[1,10] Current literature is conflicting and there is a need for additional controlled studies.[11] There may be a very small subset of patients receiving isotretinoin who are at risk for depression. It is difficult to infer if the risk is associated with isotretinoin use or another confounding variable. The incidence of depression shown in patients treated with isotretinoin is between 1% to 11% which correlates with the risk of depressive disorder in adolescents.[10] Currently, there is not enough evidence to link the relationship of depression and suicide to isotretinoin. Suicidal ideation and depression may be an adverse event that is associated with the burden of substantial acne rather than the effects of the treatment.[10]

CONCLUSION

There may never be complete agreement in the literature related to the controversies associated with isotretinoin, depression and suicide.[15] Clinicians are expected to advise their patients (and parents when appropriate) of the possible side effects of developing or progressing symptoms of depression prior to prescribing isotretinoin.[4] It is prudent to monitor patients for symptoms of depression throughout treatment. It should also be advised to report mood changes and symptoms immediately that are suggestive of depression so the patient can be evaluated for appropriate intervention.[4] When significant depression is identified, a psychiatric referral may be warranted. Since severe acne vulgaris may result in psychosocial complications, risks that

are independent of the treatment should be considered and discussed with patients.[15] There is currently not enough evidence to definitively refute or confirm an association of isotretinoin causing depression and suicide risk.[17] The limited data available would suggest that the incidence of depression and suicide during isotretinoin treatment may be comparable to the general population.[17] There is a need for further research. Additional well-designed prospective studies are required to determine causality.

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From The Patient's Perspective

What I Want You To Know About Melanoma: Words of Wisdom From a Melanoma Survivor

I was first diagnosed with Stage III melanoma when I was 22 years old. I was a high school and college cheerleader, and I will never forget having to be tan in order to cheer at games. In college, all team members received free tanning, and it was expected that we go, especially when you had skin as fair as mine.

At the time of my first diagnosis, I had just graduated from college and was waiting for my now husband to finish up graduate school. After 5 years of being scanned every 3-6 months with regular skin and doctor visits, I "graduated" from the cancer institute since the likeliness of my melanoma forming again was incredibly low.

Mindi Helmandollar-Armatas, (left) with Sancy Leachman, M.D., Ph.D.,chair of the Department of Dermatology and director of the Melanoma Research Program at the Knight Cancer Institute at OHSU.Survivor

Fast-forward to eight years later from my original Stage III diagnosis, I started to develop vitiligo on my back, and all of my eyelashes and eyebrow hair turned white. I then developed a cough. It turns out after seeing multiple doctors; I had a tumor in my lung. I had to have my lower left lung removed in order to get the tumor out. Once the tumor was tested, it turned out to be melanoma, making it Stage IV since it had metastasized from my original melanoma to my lung. The first time I was diagnosed, I did not have many friends who really understood the seriousness of melanoma, nor could I even talk about it due to the emotional toll it took.

This time around I talk openly (for the most part) about it because I have found it helps me for others to understand more about melanoma. I am also able to help raise awareness and important funds needed so a cure can hopefully be discovered.

I am so lucky to have such a huge support system, which has been a key in my recovery. My husband, parents, family, and friends have made a world of difference in helping me stay emotionally strong. If I need something, I know I can just ask, and they will help me find the answers. I know not everyone has this, and I feel so lucky I have such a huge support network. I am also taking advantage

AIM AT MELANOMA FOUNDATION

Melanoma is one of the fastest growing cancers in the United States and worldwide. It's one of the most complex forms of cancer and has the most mutations of all solid cancers.

Founded in 2004, AIM at Melanoma is the largest international melanoma foundation focused on the discovery of the cure for melanoma. AIM's global research initiatives include The International Melanoma Tissue Bank Consortium, The Melanoma International Collaboration for Adaptive Trials, and the International Melanoma Working Group.

AIM at Melanoma also provides education, connection to resources, and opportunities for meaningful engagement to help patients, caregivers, and families better face the challenges of melanoma.

For more information, visit www.AIMatMelanoma.org and follow our groundbreaking initiatives on Facebook, Twitter, and YouTube.

of all the great resources my doctor has offered and would highly recommend others to do the same such as counseling and classes about healthy eating. I have realized it is okay to accept help from others because it helps them too.

One year later after battling tumors, I am now onto my third type of chemotherapy treatment, and I finally had a clear scan! I am so incredibly grateful to all the scientists, doctors, donors, and everyone else involved in the never-ending battle to find a cure for this vicious disease.

Mindi Helmandollar-Armatas is a loving wife, teacher, student, dog lover, cheerleader, CrossFit enthusiast and coach. She is also a melanoma advocate after her own stage IV diagnosis, working to spread awareness and educate others on the dangers of the sun and tanning beds. Mindi works hard to stay positive and inspire others through being a positive role model.

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IN MODERATE-TO-SEVERE PLAQUE PSORIASIS

DEFY THE LAWS OF PSORIASIS

ILUMYA™
tildrakizumab-asmn
Injection 100 mg/mL

RESULTS WITH JUST A FEW DOSES[1,2]

- With **just 2 doses** at Week 12, 64% and 61% achieved PASI 75 (reSURFACE 1 and reSURFACE 2, respectively)
  - vs placebo: 6% and 6% (reSURFACE 1 and reSURFACE 2, respectively)
- With **just 3 doses** at Week 28, 74% and 70% achieved PASI 75 (reSURFACE 1 and reSURFACE 2, respectively)*

VISIT ILUMYAPRO.COM

LIGHTEN THE BURDEN OF FREQUENT DOSING[1,3]

- ILUMYA™ is dosed at Weeks 0, 4, and **every 12 weeks** thereafter

DURABLE SAFETY PROFILE[1]

- **Through Week 64**, the frequency of adverse reactions was similar to that during the placebo-controlled period of the trial, and no new adverse reactions were identified
- ILUMYA™ may increase the risk of infection
- The most common (≥1%) adverse reactions that were more frequent than in the placebo group are upper respiratory infections, injection-site reactions, and diarrhea

reSURFACE 1 and 2 were Phase 3, double-blind, placebo-controlled trials of ILUMYA™ given at Weeks 0, 4, and every 12 weeks thereafter. Patients in reSURFACE 1 (N=463) and reSURFACE 2 (N=463) with moderate-to-severe plaque psoriasis who were candidates for phototherapy or systemic therapy were randomized to ILUMYA™ 100 mg or placebo. At Week 28, patients in reSURFACE 1 initially randomized to ILUMYA™ who achieved at least PASI 75 were re-randomized to either continue initial treatment or to receive placebo up to 64 weeks. The co-primary endpoints of both trials were: 1) the proportion of subjects who achieved at least PASI 75 and 2) the proportion of subjects with a PGA 0 or 1 and at least a 2 point improvement, both at Week 12. Other evaluated outcomes included PASI 90/100 at Week 12 and PASI 75 at Week 28. reSURFACE 1 also measured maintenance of efficacy in responders up to Week 64.[1,2]

*These endpoints were considered "other" secondary endpoints in reSURFACE 1 and 2.
All results based on the recommended 100 mg dose of ILUMYA™.
PASI=Psoriasis Area and Severity Index; PGA=Physician Global Assessment.

INDICATION

ILUMYA™ (tildrakizumab-asmn) is indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

ILUMYA™ is contraindicated in patients with a previous serious hypersensitivity reaction to tildrakizumab or to any of the excipients.

WARNINGS AND PRECAUTIONS

Hypersensitivity
Cases of angioedema and urticaria occurred in ILUMYA™-treated subjects in clinical trials. If a serious allergic reaction occurs, discontinue ILUMYA™ immediately and initiate appropriate therapy.

Infections
ILUMYA™ may increase the risk of infection. Treatment with ILUMYA™ should not be initiated in patients with a clinically important active infection until the infection resolves or is adequately treated.

Consider the risks and benefits of treatment prior to prescribing ILUMYA™ in patients with a chronic infection or a history of recurrent infection. Instruct patients receiving ILUMYA™ to seek medical help if signs or symptoms of clinically important chronic or acute infection occur. If a patient develops a clinically important or serious infection, or is not responding to standard therapy, closely monitor and consider discontinuation of ILUMYA™ until the infection resolves.

Pretreatment Evaluation for Tuberculosis
Evaluate patients for tuberculosis (TB) infection prior to initiating treatment with ILUMYA™. Do not administer ILUMYA™ to patients with active TB infection. Initiate treatment of latent TB prior to administering ILUMYA™. Consider anti-TB therapy prior to initiation of ILUMYA™ in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed. Patients receiving ILUMYA™ should be monitored closely for signs and symptoms of active TB during and after treatment.

Immunizations
Prior to initiating therapy with ILUMYA™, consider completion of all age-appropriate immunizations according to current immunization guidelines. Patients treated with ILUMYA™ should not receive live vaccines.

Adverse Reactions
The most common (≥1%) adverse reactions associated with ILUMYA™ treatment that were more frequent than in the placebo group are upper respiratory infections, injection-site reactions, and diarrhea.

Please see Full Prescribing Information at ILUMYApro.com

References: 1. ILUMYA™ [package insert]. Princeton, NJ: Sun Pharmaceuticals, Inc. 2. Data on File. Sun Pharmaceutical Industries, Inc. 3. Rigopoulos D, Ioannides D, Chaidemenos G, et al. Patient preference study for different characteristics of systemic psoriasis treatments (Protimisis). *Dermatol Ther*. 2018;31(3):e12592.

SUN DERMATOLOGY

Brief Summary of Prescribing Information for ILUMYA™ (tildrakizumab-asmn)
ILUMYA™ (tildrakizumab-asmn) injection, for subcutaneous use
See package insert for full Prescribing Information

INDICATIONS AND USAGE ILUMYA™ is indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

CONTRAINDICATIONS
ILUMYA is contraindicated in patients with a previous serious hypersensitivity reaction to tildrakizumab or to any of the excipients *[see Warnings and Precautions]*.

WARNINGS AND PRECAUTIONS
Hypersensitivity: Cases of angioedema and urticaria occurred in ILUMYA treated subjects in clinical trials. If a serious hypersensitivity reaction occurs, discontinue ILUMYA immediately and initiate appropriate therapy *[see Adverse Reactions]*.

Infections: ILUMYA may increase the risk of infection. Although infections were slightly more common in the ILUMYA group (23%), the difference in frequency of infections between the ILUMYA group and the placebo group was less than 1% during the placebo-controlled period. However, subjects with active infections or a history of recurrent infections were not included in clinical trials. Upper respiratory infections occurred more frequently in the ILUMYA group than in the placebo group *[see Adverse Reactions]*.

The rates of serious infections for the ILUMYA group and the placebo group were ≤0.3%. Treatment with ILUMYA should not be initiated in patients with any clinically important active infection until the infection resolves or is adequately treated.

In patients with a chronic infection or a history of recurrent infection, consider the risks and benefits prior to prescribing ILUMYA. Instruct patients to seek medical help if signs or symptoms of clinically important chronic or acute infection occur. If a patient develops a clinically important or serious infection or is not responding to standard therapy, monitor the patient closely and consider discontinuation of ILUMYA until the infection resolves *[see Adverse Reactions]*.

Pretreatment Evaluation for Tuberculosis: Evaluate patients for tuberculosis (TB) infection prior to initiating treatment with ILUMYA. Initiate treatment of latent TB prior to administering ILUMYA. In clinical trials, of 55 subjects with latent TB who were concurrently treated with ILUMYA and appropriate TB prophylaxis, no subjects developed active TB (during the mean follow-up of 56.5 weeks). One other subject developed TB while receiving ILUMYA. Monitor patients for signs and symptoms of active TB during and after ILUMYA treatment. Consider anti-TB therapy prior to initiation of ILUMYA in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed. Do not administer ILUMYA to patients with active TB infection.

Immunizations: Prior to initiating therapy with ILUMYA, consider completion of all age appropriate immunizations according to current immunization guidelines. Avoid the use of live vaccines in patients treated with ILUMYA. No data are available on the response to live or inactive vaccines.

ADVERSE REACTIONS
The following serious adverse reactions are discussed elsewhere in the labeling:
Hypersensitivity Reactions *[see Warnings and Precautions]*
Infections *[see Warnings and Precautions]*

Clinical Trial 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 clinical trials, a total of 1994 subjects with plaque psoriasis were treated with ILUMYA, of which 1083 subjects were treated with ILUMYA 100 mg. Of these, 672 subjects were exposed for at least 12 months, 587 for 18 months, and 469 for 24 months.

Data from three placebo-controlled trials (Trials 1, 2, and 3) in 705 subjects (mean age 46 years, 71% males, 81% white) were pooled to evaluate the safety of ILUMYA (100 mg administered subcutaneously at Weeks 0 and 4, followed by every 12 weeks [Q12W]) *[see Clinical Studies]*.

Placebo-Controlled Period (Weeks 0-16 of Trial 1 and Weeks 0-12 of Trials 2 and 3)
In the placebo-controlled period of Trials 1, 2, and 3 in the 100 mg group, adverse events occurred in 48.2% of subjects in the ILUMYA group compared to 53.8% of subjects in the placebo group. The rates of serious adverse events were 1.4% in the ILUMYA group and 1.7% in the placebo group.

Table 1 summarizes the adverse reactions that occurred at a rate of at least 1% and at a higher rate in the ILUMYA group than in the placebo group.

Table 1: Adverse Reactions Occurring in ≥1% of Subjects in the ILUMYA Group and More Frequently than in the Placebo Group in the Plaque Psoriasis Trials 1, 2, and 3

Adverse Reaction	ILUMYA 100 mg (N=705) N (%)	Placebo (N=355) N (%)
Upper respiratory infections*	98 (14)	41 (12)
Injection site reactions†	24 (3)	7 (2)
Diarrhea	13 (2)	5 (1)

* Upper respiratory infections include nasopharyngitis, upper respiratory tract infection, viral upper respiratory tract infection, and pharyngitis.

† Injection site reactions include injection site urticaria, pruritus, pain, reaction, erythema, inflammation, edema, swelling, bruising, hematoma, and hemorrhage.

During the placebo-controlled period of Trials 1, 2, and 3, adverse reactions that occurred at rates less than 1% but greater than 0.1% in the ILUMYA group and at a higher rate than in the placebo group included dizziness and pain in extremity.

Specific Adverse Reactions
Hypersensitivity Reactions
Cases of angioedema and urticaria occurred in ILUMYA-treated subjects in clinical trials *[see Warnings and Precautions]*.

Infections
Infections were slightly more common in the ILUMYA group. The difference in frequency of infections between the ILUMYA group (23%) and the placebo group was less than 1% during the placebo-controlled period. The most common (≥1%) infections were upper respiratory infections. The rates of severe infections for the ILUMYA group and the placebo group were ≤0.3%.

Safety Through Week 52/64
Through Week 52 (Trials 1 and 3) and Week 64 (Trial 2), no new adverse reactions were identified with ILUMYA use and the frequency of the adverse reactions was similar to that observed during the placebo-controlled period.

Immunogenicity
As with all therapeutic proteins there is the potential for immunogenicity. The detection of antibody formation is highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralizing antibody) positivity in an assay may be influenced by several factors including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of incidence of antibodies to tildrakizumab in the studies described below with the incidences of antibodies in other studies or to other products may be misleading.

Up to Week 64, approximately 6.5% of subjects treated with ILUMYA 100 mg developed antibodies to tildrakizumab. Of the subjects who developed antibodies to tildrakizumab, approximately 40% (2.5% of all subjects receiving ILUMYA) had antibodies that were classified as neutralizing. Development of neutralizing antibodies to tildrakizumab was associated with lower serum tildrakizumab concentrations and reduced efficacy.

DRUG INTERACTIONS
Live Vaccinations
Avoid use of live vaccines in patients treated with ILUMYA *[see Warnings and Precautions]*.

USE IN SPECIFIC POPULATIONS
Pregnancy: Risk Summary
Limited available data with ILUMYA use in pregnant women are insufficient to inform a drug associated risk of adverse developmental outcomes. Human IgG is known to cross the placental barrier; therefore, ILUMYA may be transferred from the mother to the fetus. An embryofetal developmental study conducted with tildrakizumab in pregnant monkeys revealed no treatment-related effects to the developing fetus when tildrakizumab was administered subcutaneously during organogenesis to near parturition at doses up to 159 times the maximum recommended human dose (MRHD). When dosing was continued until parturition, a small increase in neonatal death was observed at 59 times the MRHD *[see Data]*. The clinical significance of this nonclinical finding is unknown.

All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. The background risk of major birth defects and miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

Data: *Animal Data*
In an embryofetal developmental study, subcutaneous doses up to 300 mg/kg tildrakizumab were administered to pregnant cynomolgus monkeys once every two weeks during organogenesis to gestation day 118 (22 days from parturition). No maternal or embryofetal toxicities were observed at doses up to 300 mg/kg (159 times the MRHD of 100 mg, based on AUC comparison). Tildrakizumab crossed the placenta in monkeys.

In a pre- and postnatal developmental study, subcutaneous doses up to 100 mg/kg tildrakizumab were administered to pregnant cynomolgus monkeys once every two weeks from gestation day 50 to parturition. Neonatal deaths occurred in the offspring of one control monkey, two monkeys at 10 mg/kg dose (6 times the MRHD based on AUC comparison), and four monkeys at 100 mg/kg dose (59 times the MRHD based on AUC comparison). The clinical significance of these nonclinical findings is unknown. No tildrakizumab-related adverse effects were noted in the remaining infants from birth through 6 months of age.

Lactation: Risk Summary
There are no data on the presence of tildrakizumab in human milk, the effects on the breastfed infant, or the effects on milk production. Human IgG is known to be present in human milk. Tildrakizumab was detected in the milk of monkeys *[see Data]*.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for ILUMYA and any potential adverse effects on the breastfed child from ILUMYA or from the underlying maternal condition.

Pediatric Use: Safety and effectiveness of ILUMYA in pediatric patients (<18 years of age) have not been established.

Geriatric Use: A total of 1083 subjects were exposed to ILUMYA 100 mg during Phase 2 and 3 trials. A total of 92 subjects were 65 years or older, and 17 subjects were 75 years or older. Although no differences in safety or efficacy were observed between older and younger subjects, the number of subjects aged 65 and over is not sufficient to determine whether they respond differently from younger subjects.

OVERDOSAGE: In the event of overdosage, monitor the patient for any signs or symptoms of adverse reactions and administer appropriate symptomatic treatment immediately.

PATIENT COUNSELING INFORMATION: Advise the patient and/or caregiver to read the FDA-approved patient labeling (Medication Guide).

Instruct patients and/or caregivers to read the Medication Guide before starting ILUMYA therapy and to reread the Medication Guide each time the prescription is renewed. Advise patients of the potential benefits and risks of ILUMYA.

Hypersensitivity
Advise patients to seek immediate medical attention if they experience any symptoms of serious hypersensitivity reactions *[see Warnings and Precautions]*.

Infections
Instruct patients of the importance of communicating any history of infections to the doctor and contacting their doctor if they develop any symptoms of infection *[see Warnings and Precautions]*.

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Journal Club: *Practice Changing Articles for Dermatology PAs*

Risk of Subsequent Cutaneous Melanoma in Moderately Dysplastic Nevi Excisionally Biopsied but With Positive Histologic Margins

JAMA Dermatol. 2018 Dec;154(12):1401-1408

Caroline C. Kim, MD[1]; Elizabeth G. Berry, MD[2,3]; Michael A. Marchetti, MD[4]; et al

1. Pigmented Lesion Clinic and Cutaneous Oncology Program, Department of Dermatology, Harvard Medical School, Beth Israel Deaconess Medical Center, Boston, Massachusetts
2. Department of Dermatology, Emory University School of Medicine, Atlanta, Georgia
3. Division of Dermatology, Atlanta Veterans Administration Medical Center, Decatur, Georgia
4. Dermatology Service, Department of Medicine, Memorial Sloan Kettering Cancer Center, New York, New York

Importance

Little evidence exists to guide the management of moderately dysplastic nevi excisionally biopsied without residual clinical pigmentation but with positive histologic margins (hereafter referred to as moderately dysplastic nevi with positive histologic margins).

Objective

To determine outcomes and risk for the development of subsequent cutaneous melanoma (CM) from moderately dysplastic nevi with positive histologic margins observed for 3 years or more.

Design, Setting, and Participants

A multicenter (9 US academic dermatology sites) retrospective cohort study was conducted of patients 18 years or older with moderately dysplastic nevi with positive histologic margins and 3 years or more of follow-up data collected consecutively from January 1, 1990, to August 31, 2014. Records were reviewed for patient demographics, biopsy type, pathologic findings, and development of subsequent CM at the biopsy site or elsewhere on the body. The χ^2 test, the Fisher exact test, and analysis of variance were used to assess univariate association for risk of subsequent CMs, in addition to multivariable logistic regression models. To confirm histologic grading, each site submitted 5 random representative slide cases for central dermatopathologic review. Statistical analysis was performed from October 1, 2017, to June 22, 2018.

Main Outcomes and Measures

Development of CM at a biopsy site or elsewhere on the body where there were moderately dysplastic nevi with positive histologic margins.

Results

A total of 467 moderately dysplastic nevi with positive histologic margins from 438 patients (193 women and 245 men; mean [SD] age, 46.7 [16.1] years) were evaluated. No cases developed into CM at biopsy sites, with a mean (SD) follow-up time of 6.9 (3.4) years. However, 100 patients (22.8%) developed a CM at a separate site. Results of multivariate analyses revealed that history of CM was significantly associated with the risk of development of subsequent CM at a separate site (odds ratio, 11.74; 95% CI, 5.71-24.15; P < .001), as were prior biopsied dysplastic nevi (odds ratio, 2.55; 95% CI, 1.23-5.28; *P* = .01). The results of a central dermatopathologic review revealed agreement in 35 of 40 cases (87.5%). Three of 40 cases (7.5%) were upgraded in degree of atypia; of these, 1 was interpreted as melanoma in situ. That patient remains without recurrence or evidence of CM after 5 years of follow-up.

Conclusions and Relevance

This study suggests that close observation with routine skin surveillance is a reasonable management approach for moderately dysplastic nevi with positive histologic margins. However, having 2 or more biopsied dysplastic nevi (with 1 that is a moderately dysplastic nevus) appears to be associated with increased risk for subsequent CM at a separate site.

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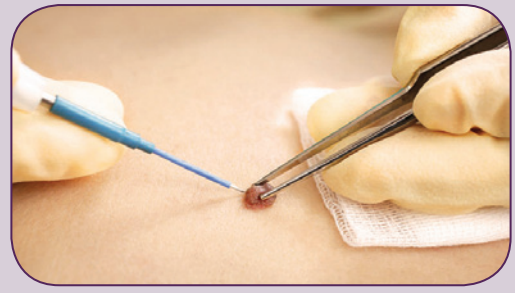
Journal clubs are a great way to review and critically evaluate the most current literature impacting the practice of dermatology. For PAs who are new to the practice of dermatology, journal clubs can assist them to become more familiar with advanced medical literature and improve their understanding of current issues within the field. The articles selected for the JDPA Journal Club are meant to be shared and discussed with your colleagues, peers, and collaborating physicians. If you have any articles to recommend for the JDPA Journal Club, please email them to editor@jdpa.org

SURGICAL wisdom

Dermcast.tv Blog - *What Are The Health Risks From Surgical Smoke?*

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

One occupational hazard faced by dermatology providers is the health effects associated with exposure to surgical smoke. Ablative lasers and electrosurgery procedures generate smoke that contains carbon and other particles that may be hazardous to one's health. While most dermatology residents receive training in how to perform procedures, few receive training on reducing smoke exposure.



A review article examined the potential hazards of smoke associated with surgical procedures and offered strategies to reduce risk. The article find that surgeons are exposed to heavy smoke plumes while performing laser surgeries, and also exposed to brief periods of heavy smoke during electrosurgery. The hazards that must be noted are exposure to infectious particles in the smoke, direct injury from exposure, and chemical and mutagenic effects.

Several studies found that HPV DNA was present in laser smoke; use of a standard surgical mask removed virtually all laser- or electrocoagulation-derived viral particles present in smoke, but in one study surgeons acquired nasopharyngeal lesions despite reporting wearing masks.

Physical effects from smoke are less conclusive, damage has been seen in animal studies, but thus far there is no study that shows direct physical injury by surgical smoke, though the authors note that it is a likely a risk that is also posed to humans.

Chemicals present in surgical smoke are ones that have been shown in studies to have negative health effects: acrylonitrile forms hydrogen cyanide and is likely carcinogenic to humans, hydrogen cyanide and carbon monoxide impede tissue oxygenation, benzene can induce headache, dizziness, nausea, and irritation of the mucous membranes. These chemicals are all present in smoke from laser tissue ablation. Though there are no human studies on smoke carcinogenesis, surgical smoke has been shown to have carcinogenic properties in vitro.

The authors state that surgical masks, HEPA respirators, and smoke evacuation systems are the most effective way to reduce risk of exposure, and this is confirmed in multiple studies. They also discuss the lack of safety training, highlighting the fact that few providers are aware that simple strategies such as a high-filtration mask will significantly reduce risk. They conclude that hazard reduction is infrequently used in clinical practice, and propose recommendations for surgical smoke protection in dermatology.

Dermcast.tv Blog Post: October 19, 2018
Source: JAMA Network
Adapted from the original article
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- The pivalate group enhances lipid solubility[1]
- Statistically significant (65%) improvement of symptoms at day 4 (versus placebo 31% P<0.001)[4]
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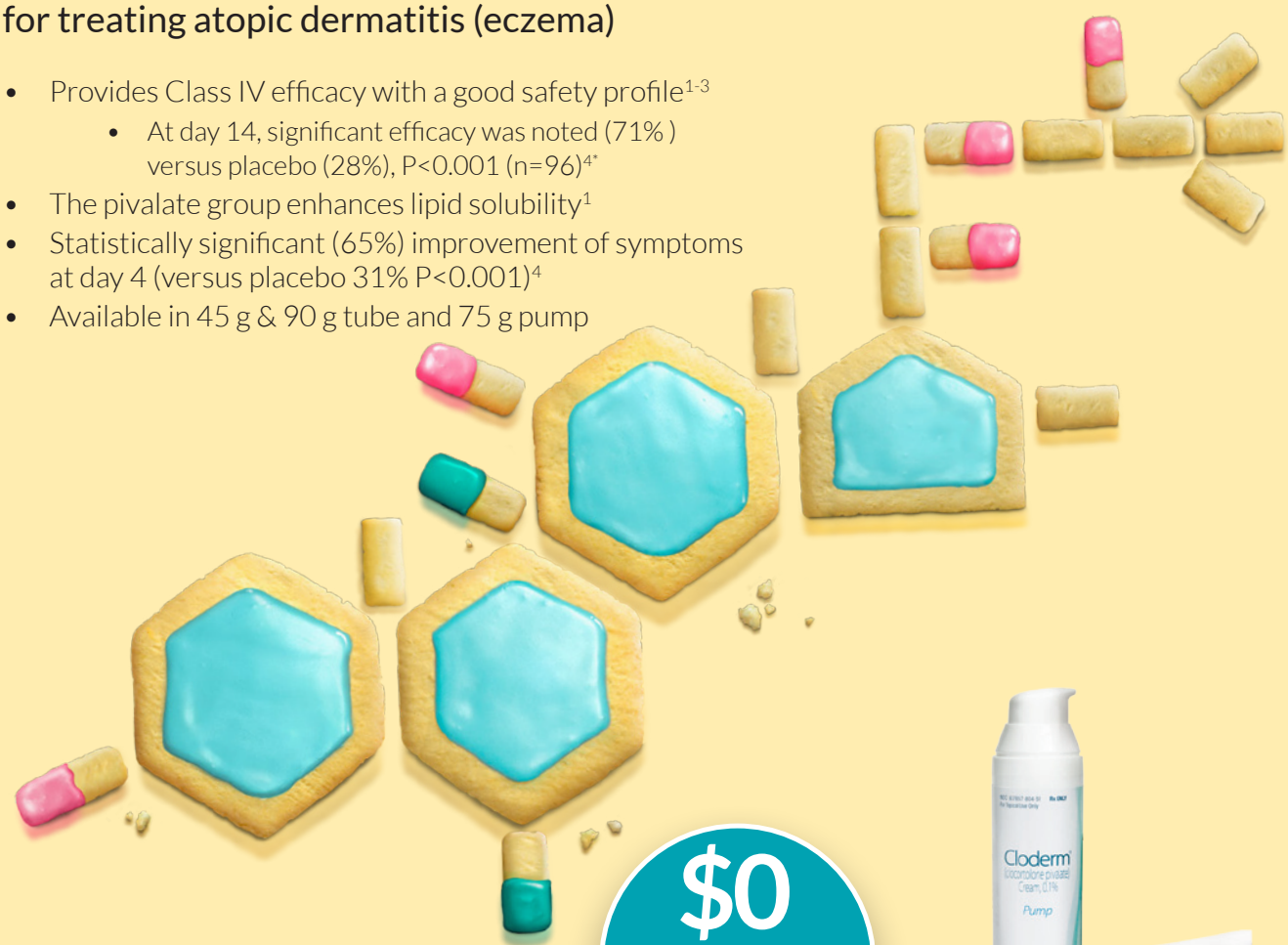

Brief Summary of Package Insert

Cloderm® Cream is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses. The most common adverse events with Cloderm® Cream include burning, itching, irritation, dryness, and folliculitis. Cloderm® Cream is contraindicated in patients who are hypersensitive to any of the ingredients of this product. As with all topical corticosteroids, systemic absorption can produce reversible HPA-axis suppression. Full prescribing information is at www.clodermcream.com

References: 1. Bikowski J, Pillai R, Shroot B. The position not the presence of the halogen in corticosteroids influences potency and side effects. J Drugs Dermatol. 2006;5(2):125-130. **2.** Del Rosso J, Friedlander SF. Corticosteroids: options in the era of steroid-sparing therapy. J Am Acad Dermatol. 2005;53(1 Suppl 1):S50-58. **3.** US Food and Drug Administration NDA 017765. Promius Pharma, LLC, Princeton, NJ: Aug 1977. **4.** Rosenthal AL. Clocortolone pivalate: a paired comparison clinical trial of a new topical steroid in eczema/atopic dermatitis. Cutis. 1980;25(1):96-98. J Am Acad Dermatol. 2005;53(1 Suppl 1):S50-58. 3. US Food and Drug Administration NDA 017765. Promius Pharma, LLC, Princeton, NJ: Aug 1977.

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Tattoo Complications May Warrant a Trip to the Dermatologist

Research indicates that 10 percent of people with tattoos experience some sort of complication, such as pain or infection. While their first inclination may be to seek help from the artist who gave them their tattoo, it may be necessary to see a board-certified dermatologist for the proper diagnosis and treatment of skin problems.

Some common tattoo complications include infections, allergic reactions and worsening of an existing skin condition such as psoriasis or eczema, says Marie Leger, MD, PhD, FAAD, a board-certified dermatologist in New York. Sarcoidosis, an autoimmune disease that can affect the skin and other organs, sometimes first appears with bumps at the site of a tattoo, she says.

Infections are more common within the first couple of days or weeks of getting a tattoo, Dr. Leger says, and they can cause redness and pain around the site of the tattoo (not just on the actual ink), drainage, crusting and pus. "If you experience these symptoms after getting a tattoo, see a doctor right away, because infections can be quite serious," Dr. Leger says.

Allergies and sarcoidosis may pop up later - months to years after getting a tattoo, Dr. Leger says. Signs of these conditions may include itching, bumps, scaling, periodic swelling or the tattoo becoming raised, she says, adding that anyone experiencing these symptoms should visit a board-certified dermatologist, rather than a tattoo artist.

"Dermatologists and tattoo artists have different categories of things that they're good with," Dr. Leger says. "Artists can assess cosmetic issues like ink migrating from the tattooed area to the surrounding area, and they're used to seeing normal tattoo healing, so they can be a useful source of information about that. Dermatologists can really help manage things like infections or chronic reactions that pop up a little later."

Dr. Leger recommends that those experiencing complications notify their tattoo artist in addition to visiting a dermatologist. "It is important for artists to know if particular patients are having complications so they can be a part of assessing what's going on," she says.

According to Dr. Leger, tattoo infections can come from contaminated ink, unsterile application or improper care after the tattoo is applied. In 2012, for example, an outbreak of tattoo infections in New York was traced back to a rare bacteria found in certain gray ink, which was then recalled. "It can be tough, because some of these things that can go wrong are in the control of artists and clients, and some aren't," Dr. Leger says.

Opened ink bottles can have more infection-causing bacteria than new bottles, she says, and it's possible for ink to become contaminated when artists mix colors or dilute with non-sterile water, which includes distilled water. She says it's important choose a reputable tattoo artist and diligently follow his or her care instructions.

Dr. Leger recommends that those with chronic skin conditions or a history of skin cancer talk to a board-certified dermatologist before getting a tattoo. People with psoriasis should be aware that they may develop a patch of the condition on their tattoo, she says, and those with moles should avoid tattooing over them. "There's no strong data that shows tattoos increase your risk of skin cancer," she says, "but they can make detection harder."

Nearly 40 percent of people born after 1980 have tattoos, Dr. Leger says, so it's important for dermatologists to be aware of potential tattoo issues and for tattoo artists to be aware of potential skin issues. To that end, she gives lectures and teaches classes for tattoo artists about skin cancer detection and preexisting skin conditions, and she also encourages her fellow dermatologists to make sure they examine patients' tattoos and look for any medical problems that may appear there.

Dr. Leger also wants the tattooed population to know that a dermatologist can help if they experience complications. "Dermatologists are the experts on skin," she says, "so if your tattoo results in a skin problem, see a board-certified dermatologist for diagnosis and treatment."

Marie Leger, MD is a board-certified dermatologist at Metro Dermatology, a private practice in New York City. Prior to joining private practice, she was an Assistant Professor of Dermatology at Weill Cornell College of Medicine for two years and at New York University for four years. She completed her dermatology residency at New York University where she also served as chief resident. Dr. Leger attended medical school at the University of Illinois where she was elected to Alpha Omega Alpha, the national medical honors society. She also earned a PhD at the University of Illinois in the Institute of Communications Research, and received her undergraduate degree in molecular and cell biology at the University of California, Berkeley.

Her research interests include tattoo health and removal, technology and health, telemedicine, and international dermatology. She treats a broad range of medical and cosmetic skin conditions, and has particular expertise in autoimmune blistering skin conditions.

Dr. Leger consults with organizations such as the FDA and New York Department of Health and Mental Hygiene about tattoo health and access to isotretinoin for acne. She started the first tattoo center in the US at Cornell University, which she now runs out of Metro Dermatology, and has lectured tattoo artists about skin health, skin cancer detection, and tattoo safety. In addition, she is the founder of a collaborative tattoo removal program at Metro Dermatology with the Legal Aid Society and the Administration for Children's Services in New York City for victims of human trafficking. She is a former host of Doctor Radio on Sirius XM. Dr. Leger is also a founding member of a teaching and research collaboration between the University of Ghana and New York University.

Dr. Leger is from the San Francisco Bay Area and has spent time working and traveling in Mexico City, Central America, and Africa. She speaks Spanish.

COSMETIC pearls

Dermcast.tv Blog

Are Plant-Based Hair Dyes Less Irritating?

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

Plant-derived dyes have been used on hair for centuries and consumers are becoming more interested in plant-based options as an alternative to chemical dyes. One of the reasons for consumer interest is the perception that plant-based hair dye may be less irritating and toxic than synthetic dye. However, plant-based dyes may still cause skin and eye irritation and they may not be as effective at saturating hair with lasting color.

A recent study sought to provide a framework to assess both dyeing efficiency and irritation potentials of formulas that combined plant colorants and hydrogel hair dyes. In the study, the dyes were directly applied to unbleached gray human hairs and the eye/skin irritancy of the formulations was evaluated by combining several in vitro methods.

The results showed that all four naturally-derived dyes had good dyeing performance on human hairs in preferred shades. The four examined plant extracts, when formulated in hydrogels, may prove a low-irritating alternative to the synthetic hair dyes. The dyes did not cause skin irritation, but some did cause eye irritation, though at similar or lesser levels than synthetic dyes.

The authors note that although their study suggests that the investigated formulas of plant hair dyes seem to be relatively innocuous to consumers, further in vivo research is necessary to better compare natural dyes to synthetic dye ingredients.

Dermcast.tv Blog Post: April 15, 2019
Source: Wiley Online
Adapted from the original article

Dermcast.tv is the official online media resource of the SDPA and is your free source for the latest SDPA-related audio podcasts, current dermatology news and research, and videos featuring thought-leaders, procedures, conference highlights, and much more. In addition, Dermcast is the #1 dermatology-related podcast on iTunes! To read more Dermcast.tv Blogs and/or to follow the next live blog from an upcoming SDPA dermatology conference, please visit the Dermcast.tv website at www.dermcast.tv and subscribe today.

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INDICATION AND USAGE

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

MINOLIRA did not demonstrate any effect on non-inflammatory acne lesions. Safety of MINOLIRA 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, MINOLIRA should be used only as indicated.

IMPORTANT SAFETY INFORMATION

- 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.
- The use of MINOLIRA during the second and third trimesters of pregnancy, infancy, and childhood up to the age of 8 years may cause permanent discoloration of the teeth (yellow-gray-brown) and reversible inhibition of bone growth.
- If pseudomembranous colitis occurs, discontinue MINOLIRA.
- If renal impairment exists, MINOLIRA doses may need to be adjusted to avoid accumulations of the drug and possible liver toxicity.
- Minocycline may cause central nervous system side effects, including light-headedness, dizziness, or vertigo.
- Minocycline may cause intracranial hypertension and autoimmune disorders in adults and adolescents. Discontinue MINOLIRA if symptoms occur.
- Minocycline has been associated with anaphylaxis,serious skin reactions, erythema multiforme, and DRESS syndrome. Discontinue MINOLIRA immediately if symptoms occur.
- The most commonly observed adverse reactions are headache, fatigue, dizziness, and pruritus.

To report SUSPECTED ADVERSE REACTIONS, contact EPI Health, LLC at 1-800-499-4468 or FDA at 1-800-FDA-1088 or visit www.fda.gov/medwatch.

For Full Prescribing Information, please visit **www.minolira.com**

REFERENCE: **1.** MinoLira Tablets [Package Insert]. Charleston, SC: EPI Health, LLC; 2018.

To learn more, please visit www.minolira.com

MIN-JAD9X12

NOTES from your Office Manager

Security of Patient Information and Health Information Technology

With virtually all medical offices and healthcare facilities connected to the internet and using computer systems for the practice of medicine, maintaining the security of computers and other electronic devices, as well as the privacy of patients' protected health information (PHI), has become critical.

The following are tips for staff and providers on securing this technology and information.

1. Require that staff and providers have strong and unique passwords:

- **a.** Passwords should have a minimum number of 12 characters and include upper and lowercase letters, numbers, and symbols.
- **b.** Passwords should be changed at set intervals.[1]
- **c.** Do not keep a written copy of your password where it would be accessible to others.
- **d.** Set short time frames for the automatic log-off of computers and devices.

2. Do not share passwords:

- **a.** Do not allow others to document in an electronic health record (EHR) under your password, while you are logged on.

3. Grant staff access to an EHR only on a "need to know" basis:

- **a.** Individuals should be granted access only to the information necessary to perform his/her job.
- **b.** If an employee transfers to a different job function, have a process in place to reduce or increase their access based on the new job functions.

4. Educate staff regarding not:

- **a.** Plugging in their personal devices to USB ports on the system's computers;
- **b.** Installing software on their work computers without prior approval;
- **c.** Clicking on suspicious links in emails; and
- **d.** Allowing USB devices to leave the facility unencrypted.

5. Position computers and printers away from patient and visitor traffic:

- **a.** Consider the use of screen filters to prevent visualization of PHI by others.

6. Encrypt all computer hard drives. At a minimum, all laptops and tablets should be encrypted, especially if they are to leave the facility.

7. Provide frequent and ongoing cybersecurity education and training.

8. Policies and procedures should clearly define the disciplinary actions to be taken for the inappropriate use of the computer system.

9. Develop a cybersecurity incident response process to address a security breach or cyber-attack, and test it at least annually to confirm that there is:

- **a.** A defined procedure for reporting any suspected information security incident;
- **b.** An obligation for employees to report any suspected incident immediately upon discovery; and
- **c.** An individual(s) with clearly assigned responsibilities for managing incidents.

10. Promptly disable an individual's access to the computer system upon their leaving employment:

- **a.** For involuntary dismissal, disable access prior to the notification of termination.
- **b.** If access to the employee's emails, voicemail, etc. is necessary, assign another qualified individual to address any information that requires review or action.

11. Maintain inventory control of all computerized devices including laptops, thumb drives, handheld devices, etc.

12. Install appropriate antivirus software and update devices frequently to protect the computer system from security vulnerabilities.

13. Perform system back-ups of files and data routinely:

- **a.** Test back-up restoration semi-annually, at a minimum.

14. Perform audits to assure compliance with health information technology policies and any applicable regulations.

[1]Current guidelines suggest that if the password length is set to 16 characters, it should be changed annually at a minimum.

Outside & Inside the 9 to 5...

Patients Are Waiting: America's Dermatology Wait Times Crisis

SDPA Partners with Greater Access for Patients Partnership (GAPP)

The SDPA leadership has been busy working behind the scenes addressing the very important topic of patient wait times. They have partnered with other patient and professional organizations through Greater Access for Patients Partnership (GAPP).

We encourage our readers to visit the SDPA webpage to read the entire report at www.dermpa.org.

According to a report released by the Greater Access for Patients Partnership (GAPP), long waits for dermatology appointments have negative physical, emotional, and lifestyle impacts on patients and caregivers. Lengthy delays for both new and returning dermatology patients have become the norm, and now average more than a month, though many patients can wait much longer for an appointment.

About the Greater Access for Patients Partnership (GAPP)

The Greater Access for Patients Partnership (GAPP) is a coalition of leading professional and patient organizations that aims to improve the dermatology wait time crisis and support access to care. Members of GAPP include the American Academy of PAs (AAPA), AIM at Melanoma, The American Health Quality Association, Derma Care Access Network, Dermatology Nurses' Association (DNA), Melanoma Research Alliance, National Eczema Association, National Alopecia Areata Foundation, Polka Dot Mama Melanoma Foundation, and Society of Dermatology Physician Assistants (SDPA).

How to Get a Quicker Dermatology Appointment

The Greater Access for Patients Partnership recommends the following five tips for patients to help them secure an appointment more quickly. If a patient of their loved ones are anxious about a skin condition or worry that a condition may become worse while waiting for an appointment, they should:

1. *Voice concerns* - Patients should know that if their skin condition causes them serious worry or physical pain, they should express these concerns when asking for an appointment. If they are still unable to get a quick appointment, they should ask the receptionist if they may speak to a medical professional on the phone or by email to advise whether their appointment should be prioritized. Serious skin infections may require an immediate visit to the emergency room.

2. *Ask for a PA or NP appointment* - Patients can ask if they can book a quicker appointment with a PA or NP. As we know, we are professionals who are highly qualified and ready to diagnose illnesses, prescribe medications, perform surgeries, and serve as a principal care providers for our patients.

3. ***Get on the waiting list*** - Patients should always ask the receptionist if there is a waiting list to receive a quicker appointment in the event that another patient cancels. If there is no waiting list, they should not be afraid to politely call back on a daily basis to check for an earlier opening.

4. ***Look into telemedicine options*** - Consider telemedicine and look into booking a dermatology appointment online. Patients can consult their health insurance providers to discuss the best possible options.

5. ***Don't wait until the last minute*** - If patients know they will need a routine appointment in the next several months, it is best to book these as soon as possible. The average wait for a follow-up dermatology appointment is six weeks and can be longer in many areas. The earlier they book an appointment, the better.

Appointment wait times for dermatology services have increased by 46% since 2009. In many cities, such as Philadelphia (78 days on average) and Cedar Rapids, Iowa (91 days), lengthy delays for both new and returning dermatology patients have become the norm. Waiting months for care has unintended physical, emotional, economic and lifestyle impacts on patients, caregivers and health systems at large. According to a 2018 survey, nearly all patients (91%) said their skin condition impacted their daily life, and half of those surveyed experienced sadness due to activities that they missed because of their skin condition and wait for a dermatology appointment. Wait times were also found to be a significant cause of anxiety. More than half (54%) reported anxiety while waiting for an appointment, and 58% worried that their skin condition would worsen while waiting. The SDPA along with the GAPP and its coalition of leading professional and patient organizations, aims to improve our country's dermatology wait time crisis and support access to quality care.

DON'T LET ACNE MARK HER JUNIOR YEAR

Epiduo® Forte (adapalene and benzoyl peroxide) **Gel 0.3%/2.5% reduces acne lesions and the risk of scarring for results your patients can see.**[1]

- Risk of scarring exists across all levels of acne severity[2]
- Reducing inflammation is fundamental in reducing the risk of scar formation[3]
- Epiduo Forte Gel significantly reduced inflammatory acne lesions and the risk of scarring through 24 weeks of treatment[1]

Important Safety Information

Indication: Epiduo® Forte (adapalene and benzoyl peroxide) Gel, 0.3%/2.5% is indicated for the topical treatment of acne vulgaris. **Adverse Events:** In the pivotal study, the most commonly reported adverse reactions (≥1%) in patients treated with Epiduo Forte Gel were skin irritation, eczema, atopic dermatitis, and skin burning sensation. **Warnings/Precautions:** Patients using Epiduo Forte Gel should avoid exposure to sunlight and sunlamps and wear sunscreen when sun exposure cannot be avoided. Erythema, scaling, dryness, stinging/burning, irritant and allergic contact dermatitis may occur with use of Epiduo Forte Gel and may necessitate discontinuation. When applying Epiduo Forte Gel, care should be taken to avoid the eyes, lips and mucous membranes.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit *www.fda.gov/Safety/MedWatch* or call 1-800-FDA-1088.

A two-phase, randomized, multicenter, investigator-blinded, vehicle-controlled trial evaluating once-daily Epiduo Forte Gel compared moderate to severe acne subjects 16 to 35 years old with a clinical diagnosis of moderate to severe acne vulgaris on the face (defined by IGA score of 3 or 4, with the same score on both sides); a minimum of 25 inflammatory lesions (papules and pustules) in total, with at least 10 on each side (excluding the nose); and no more than 2 acne nodules (≥1 cm); and ≥10 atrophic acne scars in total (>2 mm), excluding the nose. Phase 1 was a split-face, 24-week, investigator-blinded, vehicle-controlled evaluation (N=67) at 8 visits (baseline, weeks 1, 4, 8, 12, 16, 20, and 24). Phase 2 was a whole-face, open-label observation with 2 visits. Primary endpoint was scar count.[1]

Please see brief summary of full Prescribing Information on next page.

EPIDUO® FORTE
(adapalene and benzoyl peroxide) Gel 0.3% / 2.5%

A CLEARER TOMORROW STARTS TODAY

IMPORTANT INFORMATION ABOUT

EPIDUO® FORTE

(adapalene and benzoyl peroxide) GEL, 0.3% / 2.5%

BRIEF SUMMARY

This summary contains important information about EPIDUO FORTE (Ep-E-Do-Oh For-Tay) Gel. It is not meant to take the place of your doctor's instructions. Read this information carefully before you start using EPIDUO FORTE Gel. Ask your doctor or pharmacist if you do not understand any of this information or if you want to know more about EPIDUO FORTE Gel. For full Prescribing Information and Patient Information, please see the package insert.

WHAT IS EPIDUO FORTE GEL?

EPIDUO FORTE Gel is a prescription medicine used on the skin (topical) to treat acne vulgaris. Acne vulgaris is a condition in which the skin has blackheads, whiteheads and pimples.

WHO IS EPIDUO FORTE GEL FOR?

EPIDUO FORTE Gel is for use in people 12 years of age and older. It is not known if EPIDUO FORTE Gel is safe and effective for children younger than 12 years old.

Do not use EPIDUO FORTE Gel for a condition for which it was not prescribed. Do not give EPIDUO FORTE Gel to other people, even if they have the same symptoms you have. It may harm them.

WHAT SHOULD I TELL MY DOCTOR BEFORE USING EPIDUO FORTE GEL?

Before you use EPIDUO FORTE Gel, tell your doctor if you:

- have other skin problems, including cuts or sunburn.
- have any other medical conditions.
- are pregnant or planning to become pregnant. It is not known if EPIDUO FORTE Gel can harm your unborn baby. Talk to your doctor if you are pregnant or planning to become pregnant.
- are breastfeeding or plan to breastfeed. It is not known if EPIDUO FORTE Gel passes into your breast milk and if it can harm your baby. Talk to your doctor about the best way to feed your baby if you use EPIDUO FORTE Gel.

Tell your doctor about all of the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements. Using other topical acne products may increase the irritation of your skin when used with EPIDUO FORTE Gel.

WHAT SHOULD I AVOID WHILE USING EPIDUO FORTE GEL?

- You should avoid spending time in sunlight or artificial sunlight, such as tanning beds or sunlamps. EPIDUO FORTE Gel can make your skin sensitive to sun and the light from tanning beds and sunlamps. You should use sunscreen and wear a hat and clothes that cover the areas treated with EPIDUO FORTE Gel if you have to be in the sunlight.
- You should avoid weather extremes such as wind and cold as this may cause irritation to your skin.
- You should avoid applying EPIDUO FORTE Gel to cuts, abrasions and sunburned skin.
- You should avoid skin products that may dry or irritate your skin such as medicated or harsh soaps, astringents, cosmetics that have strong skin drying effects and products containing high levels of alcohol, spices or limes.
- You should avoid the use of "waxing" as a hair removal method on skin treated with EPIDUO FORTE Gel.
- EPIDUO FORTE Gel may bleach your clothes or hair. Allow EPIDUO FORTE Gel to dry completely before dressing to prevent bleaching of your clothes.

WHAT ARE THE MOST COMMON SIDE EFFECTS OF EPIDUO FORTE GEL?

EPIDUO FORTE Gel may cause serious side effects including:

- Local skin reactions. Local skin reactions are most likely to happen during the first 4 weeks of treatment and usually lessen with continued use of EPIDUO FORTE Gel. Signs and symptoms of local skin reaction include:
  - Redness
  - Dryness
  - Scaling
  - Stinging or burning

Tell your doctor right away if these side effects continue for longer than 4 weeks or get worse; you may have to stop using EPIDUO FORTE Gel.

These are not all of the possible side effects of EPIDUO FORTE Gel. For more information, ask your doctor or pharmacist.

You are encouraged to report negative side effects of prescription drugs to the FDA at *www.fda.gov/medwatch* or call 1-800-FDA-1088. You may also contact GALDERMA LABORATORIES, L.P. at 1-866-735-4137.

HOW SHOULD I USE EPIDUO FORTE GEL?

- Use EPIDUO FORTE Gel exactly as your doctor tells you to use it. EPIDUO FORTE Gel is for use on the skin only (topical). Do not use EPIDUO FORTE Gel in or on your mouth, eyes or vagina.
- Apply EPIDUO FORTE Gel 1 time a day.
- Do not use more EPIDUO FORTE Gel than you need to cover the treatment area. Using too much EPIDUO FORTE Gel or using it more than 1 time a day may increase your chance of skin irritation.

APPLYING EPIDUO FORTE GEL:

- Wash the area where the Gel will be applied with a mild or soapless cleanser and pat dry.
- EPIDUO FORTE Gel comes in a pump. Depress the pump to dispense a small amount (about the size of a pea) of EPIDUO FORTE Gel and spread a thin layer over the affected area.
- Wash your hands after applying the Gel.

WHERE SHOULD I GO FOR MORE INFORMATION ABOUT EPIDUO FORTE GEL?

- Talk to your doctor or pharmacist.
- Go to **www.EPIDUOFORTE.com** or call **1-866-735-4137.**

GALDERMA LABORATORIES, L.P., Fort Worth, Texas 76177 USA
Revised: July 2015
20089-0415-BS

GALDERMA EPIDUO® FORTE (adapalene and benzoyl peroxide) Gel 0.3% / 2.5%

References: 1. Data on file. Galderma Laboratories, L.P. **2.** Tan J, Kang S, Leyden J. Prevalence and risk factors of acne scarring among patients consulting dermatologists in the United States. *J Drugs Dermatol.* 2017;16(2):97-102. **3.** Tan J, Bourdès V, Bissonette R, et al. A retrospective study of pathogenesis of atrophic acne scars and role of macular erythema. *J Drugs Dermatol.* 2017;16(6):567-579.

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www.epiduoforte.com/hcp

Workplace Excellence

Becoming Tough-Minded

Choosing the harder, the better, the more difficult- Part 2 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.

Developing a Tough-Minded Mindset

If you look up background resources on the topic of toughness, you'll find that in the materials sciences and the science of metals, toughness refers to the ability of the materials to absorb energy - and even flexibly deform to some degree - without rupturing. So toughness in science and engineering is defined as, "Materials resistance to fracture when stressed." In a way, that's a pretty good working definition of what we mean by the development of physical, mental, and emotional toughness. Toughness we might say is *the ability of the mind, body, and spirit to resist breakdown when stressed.*

Our focus on mental toughness (or, tough-mindedness) is based on the supporting research and our experience, which shows that the physical toughness is strongly connected to mental toughness. Developing tough mindedness means developing a mindset, or a way of thinking, that puts "mind over matter" when we begin to control our perception of and tolerance for painful experiences.

Toughness, willpower, grit - these are all words used to describe what is really an overall mindset, and it is your mindset that motivates you to do the things you think you cannot, to work longer and harder than seems reasonable or feasible to achieve a goal or overcome a challenge. There is extensive research on the development of psychological assets, like mindset and flow, which shows that these can in fact be developed and expanded. *The Excellence with Integrity Mindset of Motivation Essentials* distills the supporting research into three essentials that contribute to a mindset that enhances willpower and grit.

First, the Mindset of Motivation requires you to focus on your end-goals. When we keep our eye on the desired end-goals, we're able to demonstrate willpower and grit as we push past things that are difficult, inconvenient, and uncomfortable. Second, the Mindset of Motivation requires you to take ownership of your destiny by focusing on what you can control. People become de-motivated when they begin to feel that they have no control of their situation. No matter what the challenge or

situation, you still get to choose how you'll respond. Finally, the Mindset of Motivation requires you to focus on growth and improvement. Breaking the challenge down into smaller sub-goals and then focusing on moving forward and improving is the key.

Tough-Minded Other-Study Examples

There's nothing wrong with studying typical examples of toughness; go ahead if you want to do a Rocky movie marathon - or choose whatever your favorite physical toughness and bravery movie might be. However, if we're talking about really studying examples of tough-minded performers, we need to look at some entirely different kinds of examples. For example, it would be useful to study the mindset of motivation and mental toughness of Nelson Mandela, who endured 27 years of prison, many of them alone in a 15-foot concrete cell with just a straw mat to sleep on. Looking at examples from varying contexts and situations can provide valuable insights into our own challenges. If we become students of mental toughness, we come to accept that some difficult situations requiring toughness we don't get to choose. But there are others, to which we may want to willingly subject ourselves precisely to test and develop our toughness.

Here are several different kinds of tough-minded Other-Study examples. The first is the story of Joe Simpson, a mountain climber whose true story of survival is the subject of book and documentary entitled, *Touching the Void.* Simpson was climbing to reach the peak of Siula Grande, a 21,000 foot peak in the Andes Mountains of Peru - something other people had previously attempted, but never achieved. On the descent from the top Joe broke his leg, got separated from his climbing partner, and fell into a huge crevasse (which is a gap or opening in the snow that can be hundreds of feet deep). When Joe miraculously makes it out of the crevasse he is relieved, ecstatic, even giddy. However, he quickly realizes that as great an accomplishment as he has just realized, he is still a long way away from his final goal of survival. He may be out of the crevasse, but he's still stranded alone on the top of a mountain with a broken leg. Chapter after chapter in his story show the mindset of someone who finds the will to start over again and again, all the while maintaining the grit to persevere toward his goal of surviving.

How Bad Do You Want It? is an inspirational video about former East Carolina University running back, Giavanni Ruffin, which shows both the physical and mental toughness needed to develop one's talents and abilities. His physical toughness is obviously on display, and yet what may be even more impressive is the mental toughness that drives him to this level of commitment.

The Ben Comen Story is an example of tough-mindedness that shows how mental toughness allows Ben to overcome his own personal obstacles to do things that those with much greater physical gifts could not. Unlike the example of *How Bad Do You Want It?*, the Ben Comen story shows that mental toughness isn't a book you can judge by its cover. Pound for pound I'd argue Ben Comen is every bit as tough as Giavanni Ruffin; we just don't see the character in action until he is put to the test.

In each of these Other-Study examples we see evidence of the famous quote by William Feather, in which he argues that, "Success seems to be largely a matter of hanging on after others have let go." Tough-mindedness - the individual's "resistance to fracture when stressed" - is so essential because every day in ways great and small we are stressed and put to the test, and each time we hang on and fight through we develop a higher capacity for handling the stresses we face (and, the stresses we face increase as we mature and responsibilities increase, and as our performance goals are elevated). In an athletic contest it's the game pressure, injury, fatigue, and the strength of our opponents; in the work place and in life it is often the grind and pressures of daily living.

Developing the ability of putting toughness into action consistently in numerous and varied circumstances leads to it becoming a habit or go-to character strength.

Here are some tough-mindedness optimal performance indicators:

- Persevering in spite of difficulties or challenges.
- Focusing on those things that are within your control.
- Accepting and dealing with what cannot be changed.

- Choosing to have a positive attitude and remain hopeful.
- Embracing adversity without whining, complaining, blaming, or making excuses.
- Reframing challenges and setbacks as opportunities for growth.
- Staying focused on end-goals; continuously breaking them into smaller sub-goals.
- Showing gratitude and appreciation for each new challenge and opportunity.
- Responding to adversity by working harder and smarter; holding on, pushing through, and persevering.

It is important to remember that when we work to develop tough-mindedness like nearly every character strength, we're trying to find optimal, avoiding too little or too much.

Being soft and weak isn't good, but neither is being stubborn and pigheaded! It's also important to remember, that as Coach K at Duke says, "You're not tough alone and you're not at your most confident alone." We're tougher when surrounded by our coworkers or teammates and supervisors or coaches who support and challenge us to do our best and be our best.

Make the Choice to Be Tough-Minded

If we desire to be tough-minded we must realize that it will take tough choices. *The Excellence with Integrity Tough Choices Tool* breaks down the simple but tough choices we must make to put this character strength into action.

Toughness really comes down to a series of choices we get to make, moment-to-moment, day-to-day. We get to choose our focus, our feelings, and our response. We can choose to have a positive attitude, to be courageous, and committed to work harder and smarter or, we can choose the softer, selfish pathway and choose to give up or give in.

Eleanor Roosevelt famously said, "You gain strength, courage, and confidence by every experience in which you really stop to look fear in the face. You must do the thing which you think you cannot do." Every time we make a tough-minded choice to do the thing we think we cannot, we become tougher and our confidence in our toughness grows. And thus, toughness is needed to choose the harder, the better, the more difficult - toughness also results when we do so.

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.

Listening To Patients
Retail Neurosis

By Alan Rockoff, MD

When I stopped by last August to pick up new eyeglass lenses, Harold the optician sat alone in his shop.

"Business slow in the summer?" I asked.

Harold looked morose. "I knew it would be like this when I bought the business," he said. "We're open Saturdays, but summers I close at 2 pm. Everybody's at the Cape."

Working in retail makes people more neurotic than necessary. I should know. I've been in retail for forty years.

Some time back, my patient Myrtle explained how retail induces neurosis through deforming incentives. Myrtle worked in management at a big department store. (The older among you may remember walking into buildings to buy things. You may also recall newspapers.)

"The month between Thanksgiving and Christmas makes or breaks the whole year," Myrtle said. "If you do worse than last year, you feel bad. But if you do better than last year you also feel bad, because you worry you won't be able to top it next year."

She paused. "I guess that's not a very healthy way to live, is it?"

I was too polite to agree.

Early in my career I had few patients on my schedule, maybe five on a good day. Then three of them would cancel. That was the start of my retail neurosis. Of course, I was a solo practitioner who started my own practice. The likes of me will be found in a museum someday, stuffed and mounted, along with other extinct species, under the label Medicus Cutaneus Solipsisticus (North America c. 20th century).

Over time I got busier and dropped each of my eleven part-time jobs. By now I've been busy for decades, even though I've never had much of a waiting list. Don't know why that is, but it no longer matters.

Except it does, psychologically. You won't find this in the DSM, but my working definition for the malady I describe is:

> **Retail Neurosis** (billable ICD-10 code F48.8. Other unspecified non-psychotic mental disorders, along with Writer's Block and Psychasthenia):
>
> **Definition:** The unquenchable fear that even the tiniest break in an endless churn of patients means that all patients will disappear later this afternoon, reverting the practice to the empty, formless void whence it came. Other than retirement, there is no treatment for this disorder. And maybe not then either.

You might think to classify Retail Neurosis under Financial Insecurity, but that disorder has a different code. (F40.248, Fear of Falling, Life Circumstance Problem). After all, a single well-remunerated patient (53 actinic keratoses!) can out-reimburse half a dozen others with only E/M codes and big deductibles. Treat one of the former, take the rest of the hour off, and you're financially just as well off, or even better. Yes?

No. Taking the rest of the hour off leaves you with too much time to ponder what every retailer knows: each idle minute is another lost chance to make another sale and generate revenue. That minute (and revenue) can never be retrieved. Never!

As Myrtle would say, not a very healthy way to live, is it?

Maybe not, but here as elsewhere, knowing something and fixing it are different things. Besides, brisk retail business brings a buzz, a sense of mastery and accomplishment, that is pleasantly addictive. Until it isn't.

New generations of physicians and other medical providers will work in different settings than mine; they will be wage-earners in large

organizations. These conglomerations bring their own neurosis-inducing incentives. Their managers measure providers' productivity in various deforming and crazy-making ways. (See RVU-penia, ICD-10 M26.56: "Non-working side interference." This is actually a dental code that refers to jaw position, but billing demands creativity.) Practitioner anxieties will center on being docked for not generating enough RVU's or for failure to bundle enough comorbidities for maximizing capitation payments. (e.g., Plaque Psoriasis plus Morbid Obesity plus Writer's Block.) But the youngsters will learn to get along. They'll have to.

"Taking any time off this summer?" I asked Harold.

"My wife and daughter are going out to Michigan in mid-August," he said.

"Aren't you going with them?"

"I can't swing it that week," he said. "By then people are coming back to town, getting their kids ready for school. If I go away, I would miss some customers."

Harold, you are my kind of guy!

Alan Rockoff, MD *practices dermatology in Boston, MA. He graduated with his medical degree in 1972 from the Albert Einstein College of Medicine in New York and then completed a pediatric internship and residency at Bronx Municipal Hospital Center. Continuing his education, Dr. Rockoff completed a dermatology residency program at the combined program at Boston University and Tufts University. Dr. Rockoff is a Clinical Assistant Professor of Dermatology at Tufts University School of Medicine. He has taught senior medical students and other trainees for over thirty-five years.*

Dr. Rockoff has been named one of Boston's Top Doctors by Boston Magazine for five years. Dr. Rockoff is board certified by the American Board of Pediatrics and the American Board of Dermatology. Dr. Rockoff is a Fellow of the American Academy of Dermatology and a member of the Massachusetts Medical Society and the Massachusetts Academy of Dermatology.

Dr. Rockoff's publications have appeared in a number of journals. He writes a monthly column for his dermatologic colleagues in Dermatology News as well as a blog for the magazine Psychology Today. His first book, "Under My Skin: A Dermatologist Looks at His Profession and His Patients" is available on Amazon and is his second book, "Act Like a Doctor, Think Like a Patient: Teaching Patient-focused Medicine" is available on Amazon and at Barnes and Noble.

From the Desk of...

Joe Monroe, MPAS, PA

WE KNOW WHO WE ARE

In the last two weeks, working three days a week, I saw the following cases in dermatology clinic: a 2.5cm wide melanoma (path pending), at least six BCCs, a case of koebnerizing lichen nitidus, penile "warts", which turned out to be lichen planus, a case of inverse psoriasis, another of lichen aureus, scarring alopecia secondary to discoid lupus, facial sarcoidosis, two cases of lichen striatus, and a 4cm nevus sebaceous plaque on a teenager's face.

During that time, I also performed twelve excisions, mostly from the face, as well as twenty or so biopsies, several to rule out serious diseases such as cutaneous T-cell lymphoma, sarcoidosis, and, yes, Hansen's disease.

That's about forty patients a day, and only once did I "pop a pimple", that being a 4cm highly fluctuant acne cyst on a young man's neck, which yielded copious amounts of cheesy, odoriferous contents, which soaked a 6 inch stack of 4 by 4's, some of which splashed onto my jacket. At least two others in the room at that time almost fainted at this sight and smell. I can't say I enjoyed it, but one learns, after twenty-five years or so, to automatically breath through one's mouth for a bit.

The point? Those outside our precious specialty, including most physicians, have no idea of the depth and breadth of what dermatology providers do. If we were inclined to self-pity, we might feel like the Rodney Daingerfields of the medical world, considering how little respect we get. And to add insult to injury, being mere "assistants", we often endure this exchange when getting acquainted with someone we just met:

"And what do you do for a living?" they ask.

"I'm a physician assistant practicing dermatology."

"Oh, who do you work for?"

"I don't work for anyone. I practice at XYZ Clinic with a fellow PA, and our dermatologist, Dr. Smith."

"Oh, I thought you were an assistant."

"Well, one would think so, and some actually do assist the physician, but most simply practice medicine, which is what I do."

I won't bore you with the rest of the conversation, because all of you have had it, many, many times. Like Rodney, "We don't get no respect."

But, at the same time, we are in possession of a very well kept secret. That being the fact that, in surmounting the steep learning curve, we have earned the privilege of functioning as competent providers in the most interesting, fascinating, challenging specialty one could imagine, which means we know thousands of diagnoses no one else has even heard of, let alone diagnosed. We are the only Swahili speakers who can translate the skin's strange language. Only we know how Sherlockian, how incredibly difficult, but how deeply satisfying mastering this skill is. We know, and that is enough.

Joe Monroe, MPAS, PA *is the founder of the SDPA as well as a past President. He is currently retired. He recruited, trained, and still mentors his PA successor at Epiphany Dermatology in Tulsa. He was working part-time when he authored this article. In addition to volunteering at free clinics in the Tulsa area, he writes for several online and print journals, and will continue to teach PA students as well as internal medicine residents.*

Philadelphia Physicians Honored For Teamwork

Dermatologist and infectious disease specialist work together to treat patient with leprosy

The American Academy of Dermatology has honored Carrie Kovarik, MD, FAAD, and Keith Hamilton, MD, as Patient Care Heroes for their collaboration to improve patient care. Both physicians teach and practice medicine at the Perelman School of Medicine at the University of Pennsylvania in Philadelphia.

Because Dr. Hamilton, an infectious disease specialist, knew that Dr. Kovarik, a dermatologist, had significant international experience, he asked her to help with a patient with a suspected case of leprosy, a well-known condition that is quite rare in the United States. Dr. Kovarik confirmed a diagnosis of lepromatous leprosy.

"In addition to antibiotics, treating leprosy involves suppressing the immune system, something that dermatologists are familiar with from their work treating psoriasis and other autoimmune conditions," Dr. Hamilton said. "Dr. Kovarik was incredibly helpful in ensuring this patient received the best possible care."

Drs. Kovarik and Hamilton saw the patient, who had traveled abroad, during a joint visit, and together they devised an appropriate treatment plan. They continued to collaborate as the patient healed, making adjustments as needed.

"Collaborative relationships between doctors who work in different specialties is essential for good patient care, especially with complicated cases," Dr. Kovarik said. "There are a lot of factors that can make collaboration and coordination among doctors complicated, but we know it is essential to providing patients with the best possible care."

The AAD created the Patient Care Heroes program to recognize physicians who transform patients' lives by utilizing their expertise and collaborating with other physicians to treat serious skin disease.

"Patients are increasingly seeing a team of clinicians, not just one doctor, so it's incredibly important, and rewarding, for physicians to build relationships across specialties and draw from one another's expertise," said Suzanne Olbricht, MD, FAAD, president of the AAD. "The partnership between Drs. Kovarik and Hamilton improved the patient's care and resulted in a better experience. That's a win-win for everyone, especially our patients."

Keith Hamilton, MD *received his undergraduate degree in Chemistry from Franklin and Marshall College and his medical doctorate from the University of Pennsylvania. He completed internal medicine residency and infectious diseases fellowship at the Hospital of the University of Pennsylvania. Dr. Hamilton is currently an Assistant Professor of Clinical Medicine in the Division of Infectious Diseases at the Perelman School of Medicine at the University of Pennsylvania. He is Director of Antimicrobial Stewardship, Co-Chair of the Antibiotic Subcommittee of the Pharmacy and Therapeutics Committee, Vice-Chair of the Pharmacy and Therapeutics Committee, and Associate Healthcare Epidemiologist at the Hospital of the University of Pennsylvania. He also has an interest in medical education, and he is the Director of the Internal Medicine Clerkship and Associate Director of Undergraduate Medical Education in the Department of Medicine. His clinical interests include treatment of general infectious diseases, multi drug-resistant infections, and mycobacterial infections. He is the Co-Founder and Co-Director of the Mycobacterial Co-Management Clinic at the Hospital of the University of Pennsylvania.*

Carrie L. Kovarik, MD *is an Associate Professor of Dermatology, Dermatopathology, and Medicine at the University of Pennsylvania. Dr. Kovarik has a special interest in global and community health, telemedicine, informatics, and HIV-related skin disease. She created the Penn Dermatology Global Health program, through which she works to provide clinical care and education in developing countries and underserved communities in the United States. Dr. Kovarik is the Head of Dermatology, Informatics, and Telemedicine for the Botswana-UPenn Partnership and has created a global telemedicine consult service which is a collaborative effort between Ministries of Health, local telecommunication and software companies, universities, specialty organizations, numerous countries, and local governments. She is currently also focusing on expanding, sustaining, and researching new models of health care that increase access to care through telemedicine.*

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.

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