AAD

DermWorld meeting news

A Publication of the American Academy of Dermatology | Association

Sunday • March 10, 2024

See Exhibit Hall floor plan and exhibitor listing.
PAGES 12-14

HAPPENING TODAY

AAD/A Annual Business Meeting
8-8:45 a.m.
Location: Room 20B

Plenary lineup
8:45-11:30 a.m.
Location: Room 20B

8:45 a.m.
Chair's Welcome
Hensin Tsao, MD, PhD, FAAD

8:50 a.m.
Clarence S. Livingood, MD Memorial Award and Lectureship: Photodermatology: Past, Present, and Future
Henry W. Lim, MD, FAAD

9:15 a.m.
President's Address
Terrence A. Cronin Jr., MD, FAAD

9:30 a.m.
Lila and Murray Gruber Memorial Cancer Research Award and Lectureship: Imatinib as a Paradigm of Targeted Cancer Therapies
Brian J. Druker, MD

9:55 a.m.
President-Elect Address
Seemal R. Desai, MD, FAAD

10:10 a.m.
Marion B. Sulzberger, MD Memorial Award and Lectureship: Sensing Inflammation at the Barrier
Brian S. Kim, MD, MTR, FAAD

10:35 a.m.
John Kenney Jr., MD Lifetime Achievement Award and Lectureship: Health Equity in Dermatology: What Can I Do?
Patricia Treadwell, MD, FAAD

10:55 a.m.
Keynote Speaker
William Shatner

A welcome relief

Effective therapies now available for hidradenitis suppurativa.

The biology of hidradenitis suppurativa (HS), also known as acne inversa, is not always understood, which has limited the development of effective therapies for this chronic inflammatory skin condition predominant among women and minoritized patient groups — until now. Recent treatment advancements include novel therapeutics and office-based surgical and laser therapies.

Saturday's session, S033 – Hidradenitis Suppurativa/Acne Inversa (HS/AI): Current Medical and Surgical Management, brought renewed attention to the condition and hope for patients, said session director Haley Naik, MD, FAAD, associate professor of dermatology at the University of California, San Francisco (UCSF) School of Medicine.

"With recent advances in the field, there are now several novel and effective therapies that are either FDA-approved, in the pipeline to approval, or otherwise available to care for this underserved patient population," said Dr. Naik.

Serious and complex

HS can present as deep-seated nodules and abscesses, draining dermal tunnels, and fibrotic scars most commonly in intertriginous areas, such as the axillary, groin, perianal, perineal, and inframammary locations. Dr. Naik and a panel of experts provided an overview of HS epidemiology, etiology, and comorbidities, and the latest advancements in the medical and office-based surgical and laser therapies for HS, including how to access them for your patients and how to ensure that your patients feel confident about trying these treatments.

"Understanding the patient journey, eliciting treatment goals, and helping patients navigate the health care system are keys to caring for patients with HS," said Dr. Naik, who provides specialty care for patients with HS in the context of the UCSF Hidradenitis Suppurativa Clinic, which she established in 2016.

"Understanding the patient journey, eliciting treatment goals, and helping patients navigate the health care system are keys to caring for patients with HS."
– Haley Naik, MD, FAAD

Bench to bedside applications

To support dermatologists in providing up-to-date care to their HS patients, panelists presented clinically relevant data on novel therapeutics for HS, including the recently FDA-approved therapy secukinumab, and non-biologic and non-small molecule inhibitor therapies that show promise for HS as well as pain management and office-based procedures. They also highlighted therapies you can expect to see coming down the pipeline in the next year or so, including novel interleukin (IL)-17, IL-1, and Janus kinase (JAK) inhibitors for the treatment of HS.

Experts weigh in

The session also included presentations by panelists Ra'ed Alhusayen, MD, MSc, FAAD, "Epidemiology and Comorbidities of HS;" Leandra Alicia Barnes, MD, FAAD, "Optimizing the HS Clinic Visit;" John Frew, MBBS, IFAAD, "Pathophysiology of HS;" Daniel Mark Klufas, MD, FAAD, "Office-Based Surgical Procedures for HS;" Tiffany Mayo, MD, FAAD, "Overcoming Barriers to Therapeutic Access;" Robert Micheletti, MD, FAAD, "HS Medical Management With Biologics and Small Molecule Inhibitors;" and Lauren Orenstein, MD, FAAD, "HS Pain Management."

Collectively, panelists discussed tools to access the latest novel treatments for people living with HS, such as secukinumab, and how to effectively use existing HS therapies, including infliximab, ertapenem, and biosimilar drugs.

Attendees also came away with a roadmap for coordinating the care of complex comorbid conditions in collaboration with primary care and specialties including surgery, pain management services, counseling services, rheumatology, and obstetrics and gynecology.

Moving the needle

Although the AAD's Hidradenitis Suppurativa Symposium has been ongoing for over a decade, these recent advancements make it an especially opportune time to put HS on your radar, Dr. Naik said.

"We have never as a specialty or field been better positioned to care for our patients who live with HS than we are today," she said. "As physicians who deeply care for our patients, this is a gratifying moment in which to practice." ●

Get social!

Follow @AADmember on Facebook, Instagram, and X (formerly Twitter). Share your experiences and photos with friends and colleagues using the official meeting hashtag **#AAD2024**. Look for the giant AAD letters for a fun photo opp and participate in the daily challenges on X and Instagram!

See page 15 for more details.

Inside

I am modernizing dermatology

The business and practice of dermatology never stops evolving... and neither do I. That's why I choose solutions that help prepare me for the challenges of today and set me up for success in the future. Innovations that help ease staffing and scheduling concerns, minimize billing and revenue shortfalls, and simplify patient communication at every step.

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Who will be the future leaders of the Academy?

The Nominating Committee voted to present the following slate of candidates (listed in random order) for the 2024 Academy election of Officers, Directors, and Nominating Committee Member Representatives (West Region).

Visit the AAD Election Connection at **aad.org/election** to learn about this year's candidates and to interact with them on top issues via the online Ask the Candidates forum.

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Glenn D. Goldman, MD, FAAD

A. Shadi Kourosh, MD, MPH, FAAD

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Cory Rubin, MD, FAAD

Easily vote using personalized voting link beginning March 9.

Eligible voting members can easily vote using their personalized voting link starting March 9. Watch your email inbox for voting reminders that include this link. Members can access the AAD Election Connection at **aad.org/election** to view/print the election ballot book and learn more about the candidates.

Hot spot!

Nearly 100 firefighters received a skin check and education about cancer in the Sails Pavilion on Saturday. The checks were performed by 20 volunteer AAD members to kick off the Academy's new Firefighter Skin Cancer Checks program, which launches nationally this summer. We even caught a suspected melanoma.

TODAY'S HIGHLIGHTS

S047 – Up-to-Date Treatment of Hair, Scalp, and Nail Disorders
1-4 p.m.
Location: Room 6A

S048 – It's Complicated: Lasers, Fillers, and Surgical Complications
1-4 p.m.
Location: Room 31B

S050 – Late-Breaking Research: Session 2
1-4 p.m.
Location: Room 20B

S052 – Atopic Dermatitis
1-4 p.m.
Location: Room 6B

S053 – Boards Blitz
1-4 p.m.
Location: Room 1B

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If you see a waterfall,
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That worrisome rash

Tackling pediatric allergic contact dermatitis ASAP.

Allergic contact dermatitis is estimated to affect

about 20%
of the world's general population

and

nearly 20%
of children with atopic dermatitis

TOP TRIGGERS:

Metals
Such as nickel and cobalt

Preservatives
Such as methylisothiazolinone and formaldehyde

Sudsing agents
Such as cocamidopropyl betaine and glucosides

Fragrances


JiaDe Yu, MD, FAAD

There's good reason to rapidly pursue more answers for managing pediatric cases of allergic contact dermatitis. Currently, there are no treatments for allergic contact dermatitis in children except avoidance.

Allergic contact dermatitis occurs at a high prevalence, according to JiaDe Yu, MD, FAAD, professor of adult and pediatric dermatology at Harvard Medical School in Boston. Dr. Yu, who was the director of Saturday's session, F047 – Considerations in Allergic Contact Dermatitis, said it is estimated to affect about 20% of the world's general population, and nearly 20% of children with atopic dermatitis, making it an important diagnosis to consider in the clinical setting.

"The goal of our session is to introduce several important concepts, including how to patch test children, what to patch test them to, and finally giving the audience the realization that patch testing in children with atopic dermatitis that is atypical in presentation or response to treatment may yield steroid/systemic-sparing outcomes," Dr. Yu said.

Top 10 triggers

Part of the session explored the most up-to-date data on the prevalence of contact allergens in children, as published by the North American Contact Dermatitis Group and other international study groups. Another focus was on the top 10 trending allergens affecting children. According to Dr. Yu, the top allergens in children include metals such as nickel and cobalt, preservatives such as methylisothiazolinone and formaldehyde, sudsing agents such as cocamidopropyl betaine and glucosides, and fragrances.

"These are found everywhere in common day-to-day personal care products, toys, chairs at school, homemade slime, etc.," he said.

Dr. Yu and his researchers are currently studying contact allergens in children, particularly those with atopic dermatitis, to show that children can develop both allergic contact dermatitis and atopic dermatitis. Another area of study, he said, is whether patch testing while on a systemic treatment for atopic dermatitis, such as dupilumab, can still provide accuracy.

Avoidance may be best

Without effective treatment for allergic contact dermatitis, the session explored ways to avoid triggers as well as when to patch test. Patch testing is important in children to detect underlying causes of eczematous rashes that may not look like or respond to typical atopic dermatitis treatments. According to Dr. Yu, patch testing young children requires a special technique and an extra judicious selection of allergens.

"Not patch testing children could potentially miss cases of superimposed allergic contact dermatitis, placing children unnecessarily on systemic treatments of atopic dermatitis," he said.

Session panelists also provided guidance in the detection of photoallergies in children and their mimickers. Photoallergies in children is an understudied field, Dr. Yu said. The most common causes of photoallergies in children, he said, are chemical sunscreen filters. Physical blockers like zinc and titanium are uncommon causes. Other additives in sunscreens can also cause photoallergies, though phototesting done only at special centers can detect this.

"Mimickers of photoallergy in children are vast and can include allergic contact dermatitis, polymorphous light eruption, juvenile spring eruption, drug photosensitivity, photoirritant dermatitis, or solar urticaria, just to name a few," Dr. Yu said.

Other presenters included Brandon L. Adler, MD, FAAD; Paul Lorenzo Bigliardi, MD, IFAAD; Shaina George; Margo Reeder, MD, FAAD; and Mykayla Sandler. ●

> "Not patch testing children could potentially miss cases of superimposed allergic contact dermatitis, placing children unnecessarily on systemic treatments of atopic dermatitis."
>
> – JiaDe Yu, MD, FAAD

Fox Award: The future of dermatology recognized

The Residents and Fellows Symposium was held Saturday, during the 2024 AAD Annual Meeting in San Diego, led by Cory A. Dunnick, MD, FAAD. Faculty judges selected individuals who presented the most outstanding papers in laboratory and clinical research. The winners of this year's prestigious Everett C. Fox Memorial Award are listed below.

Congratulations to all who participated in the 2024 Resident and Fellows Symposium!

Basic Science Category

Winner name: Kevin Severson, MD
Title: Clinical, Pathological, and Molecular Changes of Intermediate-to-High Risk Cutaneous Squamous Cell Carcinoma (cSCC)

Winner name: Amy Petty, MD
Title: Single Cell RNA Sequencing Reveals Complex Keratinocyte Landscape in Acute and Chronic Cutaneous Graft-versus-Host Disease

Winner name: Conor Broderick
Title: Associations Between the Early-Life Skin Microbiome And Hygiene-Related Exposures, Including Infant Skin Care

Winner name: Isara Yenyuwadee, MD
Title: The Efficacy of Nail Gutter Method for Epidermal Growth Factor Receptor Inhibitors-Induced Nail Changes: A Randomized, Single-Blinded, Intra-Individual Study

Clinical Category

Winner name: Kyle Lauk, MD
Title: Sexual Dysfunction With 5-Alpha-Reductase Inhibitor Therapy for Androgenetic Alopecia: A Global, Propensity Score Matched, Retrospective Cohort Study

Winner name: João Nuno Soares
Title: Decoding ß-Lactam Cross-Reactivity: Longitudinal Skin Testing From 2015-2022

RESIDENT JEOPARDY

New champs announced

Winning team: Einstein Bros.
Albert Einstein School of Medicine
Jose Jaller, MD
Suraj Reddy Muddasani, MD

Off label, on point

Spironolactone can be an effective treatment for patients with acne.

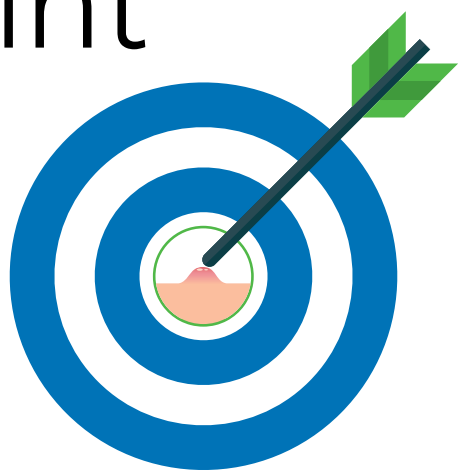
Emmy Graber, MBA, MD, FAAD, founder and director of the Dermatology Institute of Boston

Spironolactone is primarily used for the treatment of heart failure, high blood pressure, or hypokalemia — but more than a few dermatologists know that it can also be a secret weapon for treating acne in women.

Emmy Graber, MBA, MD, FAAD, founder and director of the Dermatology Institute of Boston, said that in spite of it being used for acne treatment for years, some dermatologists remain a little uncertain about using it today.

"It has FDA approval for other indications, but not for treating acne, and for that reason, some dermatologists are a little hesitant to use it for acne because it is an off-label use," she said.

The use of spironolactone was explored by Dr. Graber and other presenters, including Hilary Baldwin, MD, FAAD, Julie Claire Harper, MD, FAAD, and Bethanee Jean Schlosser, MD, PhD, FAAD, in Friday's session, F021 – Practical Guidelines for Using Spironolactone in Acne Patients.



Pinpointing the patient

One of the keys to effectively using the drug, Dr. Graber explained, is knowing who will benefit the most. For example, she said spironolactone is primarily used in women because of its potential side effects (such as gynecomastia) in men. But there are other factors to consider in deciding who is — and isn't — a good candidate.

"You have to look at the age of the patient when we might start treatment," Dr. Graber said. "It also depends on what type of acne they have. We used to think that patients who were good candidates had primarily lower face or jawline acne, but that's not necessarily the case anymore."

Dr. Graber said dermatologists also must know when it is appropriate to do a lab workup in patients who may benefit from spironolactone treatment.

"Do we think that everyone whose acne flares up around the time of the menstrual cycle needs a hormonal (lab) workup for that acne?" she asked. "Probably not, but there are some telltale signs to look for, such as hirsutism, a deepening of the voice, and irregular periods, which may warrant a laboratory workup."

Consider the side effects

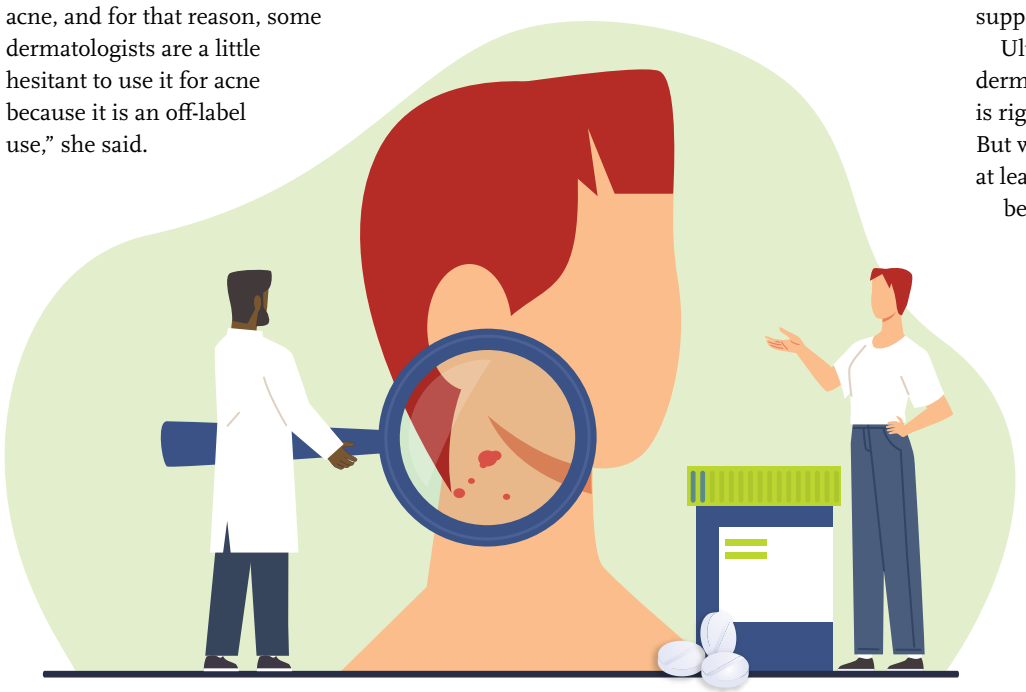
As with any drug, there are potential side effects to consider with spironolactone, such as irregular menstrual cycles and the potential for hyperkalemia.

Dr. Graber said there has long been concern over the possibility of breast cancer as well.

"Some physicians are leery of putting patients on spironolactone because of breast cancer concerns, but this is not supported by scientific studies," she said.

Ultimately, Dr. Graber said it is up to dermatologists to decide if spironolactone is right for them and for their patients. But whether they use it or not, they should at least be aware of its potential and its benefits to the medical community.

"It is of particular interest to dermatologists because, although it is off-label, it can be a very successful treatment for acne," she said. "In this era of antibiotic stewardship, we're using antibiotics more selectively these days, so we want alternatives, and this is a non-antibiotic alternative that dermatologists should consider. It's been proven to be an effective drug for treating acne." ●



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It's personal

Expansive treatment regimen available for acquired pigmentary disorders.

Sandy Sharon Tsao, MD, FAAD, assistant professor of dermatology at Harvard Medical School in Boston

Arianne Shadi Kourosh, MD, MPH, FAAD, associate professor of dermatology at Harvard Medical School

Few disease phenotypes are as visually compelling, or as challenging to treat, as chronic hyperpigmentation. But now it's getting personal. The increase in the treatment of acquired pigmentary disorders — approximately 1.5 million dermatology visits annually in the U.S. — has provided a wealth of background information and new opportunities to personalize a corrective regimen.

That was welcome news for dermatologists who attended Friday's session, F022 – Fifty Shades of Brown: Science, Symptoms, and Strategies for Acquired Pigmentary Disorders. Sandy Sharon Tsao, MD, FAAD, who led the session, credits rapid advances in molecular and biologic therapeutics and breakthroughs in device technology with bringing hope to patients. Dr. Tsao is an assistant professor of dermatology at Harvard Medical School in Boston.

"Every individual has a unique ethnic background, history of environmental exposures, history of response to injuries, and family history. The personalization in diagnosing dyschromias is in determining these unique factors to help tailor your treatment plan to that individual," Dr. Tsao said.

Getting it right, globally

Acquired pigmentary disorders, such as post-inflammatory hyperpigmentation and melasma, represent some of the most common cutaneous concerns globally. For many years, according to session presenter, Arianne Shadi Kourosh, MD, MPH, FAAD, associate professor of dermatology at Harvard Medical School, the treatment approach focused on targeting the tyrosinase enzyme in the pathway of melanin production. In recent years, however, researchers are looking at other pathways, including the interaction of melanocytes with keratinocytes.

"It is also important that other environmental triggers and exacerbating factors beyond ultraviolet radiation and their role in worsening hyperpigmentation have become a greater focus of research and public education, such as visible light, heat or infrared radiation, and pollution," Dr. Kourosh said. "For years, I have been concerned and lecturing about the role of pollution in dyschromia and skin aging, especially in caring for people who traveled to our clinic from countries in the world with high pollution levels. Now with rising air pollution in certain regions of the U.S. (hitting peak levels in the northeast in 2023), it could be an increasingly relevant trigger for patients."

Proper diagnosis is the first step toward treating the disorder. And that requires a thorough patient history, Dr. Tsao said. Dermatologists should be asking patients about the duration of the pigmentary changes, exploring whether there is a known underlying causal etiology for the changes, if injury is an isolated or ongoing event, treatment and response history, family history, a physical exam with attention to the location of the pigmentary changes, and ethnicity.

"Consideration of ethnic background comes into play when considering specific medical dyschromia, including ashy dermatosis, lichen planopilaris post-inflammatory hyperpigmentation, and melasma," Dr. Tsao said. "These conditions present more commonly in patients of specific ethnic backgrounds, requiring a broader consideration for underlying diagnoses."

Risk assessment

Individuals with darker skin phototypes may be at higher risk of exacerbating their dyschromia when exposed to ultraviolet or visible light as well as excessive heat, according to Dr. Tsao. Patients with darker skin phototypes respond more vigorously to many treatment options, with a higher risk of post-inflammatory hyperpigmentation and scar formation, which must be considered when determining a treatment plan.

"Understanding how to determine the risk/benefit profile, having the correct treatment agents and devices in your office, and how to provide the appropriate treatments is critical for safe and effective outcomes," Dr. Tsao said.

What's right for your patient?

Current and future medical, surgical, or combination treatment strategies have evolved.

Current treatment strategies include preventative measures, topical medications, oral medications, peeling agents, resurfacing procedures, PRP, and microneedling technologies.

More recently, the use of oral antioxidants has come into play as preventative agents. These include vitamin E, polypodium leucotomos, niacinamide, pyconogenol, grapeseed extract, and glutathione.

Preventative measures including recognizing the role that visible and ultraviolet light play in exacerbating dyschromia is vital to minimizing further development of pigmentary changes. Maximizing sun protective measures is critical, including daily broad-spectrum tinted sunscreen use with physical blocking agents, like titanium dioxide, zinc oxide, and iron oxide. Sun-protective clothing is paramount.

Combination treatments
Specifically, combining preventative measures, maximizing topical therapies, and using conservative treatments such as peels and laser/energy-based devices will maximize treatment outcomes. A thorough understanding of the interactions of combination therapies is necessary to minimize potential side effects.

Making an effective, tailored treatment plan for each unique patient requires:

- Taking a thorough history
- Ensuring a correct diagnosis for the underlying dyschromia
- Evaluating past treatment responses
- Understanding the risk profile of each treatment
- Identifying triggers

Identifying triggers is key
Without removal of triggers, the problem could perpetuate and even the best therapies could be limited in their impact. Addressing triggers for a person's hyperpigmentation is critical to tailoring the right treatment plan.

New and breakthrough treatment

Currently, a combination of topical and oral medical therapies as well as laser treatments and chemical peels are used with varied efficacy depending on the causes and levels of depth in the skin affected in the dyschromia, according to Dr. Kourosh. With laser treatments and chemical peels, the heat or irritation caused by some of these procedural treatments (if they are not in the hands of a highly skilled dermatologist) can worsen the problem.

"This is especially concerning for my patients with darker skin types who are more vulnerable to hyperpigmentation from these treatments and who have suffered and been burned in some cases by practitioners who were not sufficiently trained in the care of their skin. New treatments are in the pipeline and more are needed," Dr. Kourosh said.

Dr. Tsao offered more on recent scientific breakthroughs in the understanding of normal melanocyte biology and abnormal pigment physiology have been key to treatment regimens, including advances in the understanding of abnormal pigment physiology. This focuses on the effects of UV as well as visible light-induced skin injury, and the influence of inflammation and skin barrier dysfunction.

These changes include increased expression of VEGF, increased dermal vessels, basement membrane damage, increased WNT expression, increased mast cell production, increased fibroblast senescence, oxidative stress, and increased estrogen and progesterone receptors. In the future, Dr. Tsao said, a better understanding of the role of these changes will allow for the development of more targeted therapies.

The emotional toll

Dr. Kourosh reminds dermatologists of the emotional toll the disorder takes on patients as well as the need for public health education on the problems that arise from cultural pressures surrounding colorism and the unsafe skin bleaching practices in our society.

"I have developed a deep appreciation and empathy for struggles these patients face, feeling disfigured especially in the challenging cases that persist despite all of our current therapies," she said.

"We need to improve treatments for pigmentary problems, while also improving medical education and public education to protect patients from misinformation and threats to the health of their skin and well-being, and promote a more diverse ideal of beauty and healthy skin." ●

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Exhibit Hall Map

Exhibit Hall hours
Sunday | 10 a.m.-3 p.m.

Exhibitor Listing

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Sails Pavilion
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EXHIBITOR LISTING

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Follow @AADmember to win big at Annual Meeting!

#AAD2024

What could be better than being in San Diego with all your favorite colleagues? Winning daily giveaways, of course! The @AADmember accounts are hosting new **social media challenges each day of the 2024 AAD Annual Meeting, from Friday, March 8, until Monday, March 11**.

Each day, a post will be shared on Instagram and X (formerly Twitter) that will ask attendees to participate in a new type of challenge. One randomly selected winner will be chosen on each platform to receive a daily giveaway. Prizes will include everything from $100 gift cards to registration discounts for future AAD meetings. Attendees are encouraged to participate on both platforms to double down on the fun and increase their chances of winning. In addition to offering sizzling prizes, the @AADmember accounts will also be sharing tons of photos and updates about the meeting that you won't want to miss. Be sure to include the official meeting hashtag **#AAD2024** in all your posts to see if your content gets reshared by the AAD! ●

For more information, see the official rules and regulations online at aadmeetingnews.org/22886745 *or direct message @AADmember on X (formerly Twitter) or Instagram.*

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aad.org/mobile

- Session schedules
- Exhibitor information
- CME
- Session evaluations

Pearls from both sides of the pond

American and European dermatologists share news on upcoming treatments.

Jeffrey Callen, MD, FAAD, FACP, MACR, professor of medicine and chief of the division of dermatology at the University of Louisville School of Medicine in Kentucky

S059 – The Best of American and European Dermatology
1-4 p.m. | Monday, March 11
Location: Room 6F

Pustular psoriasis is a rare, but serious condition. The good news for dermatologists and their patients is that there are at least two new treatments in the pipeline for pustular psoriasis and other conditions, which may change the way they are managed in the near future.

Jeffrey Callen, MD, FAAD, FACP, MACR, professor of medicine and chief of the division of dermatology at the University of Louisville School of Medicine in Kentucky, said intravenous spesolimab has been approved as a treatment for generalized pustular psoriasis, but it may have even more uses than that. Dr. Callen is the director of Monday's session, S059 – The Best of American and European Dermatology.

"It might eventually be approved as an SQ injection for pustular psoriasis of the palms and soles," Dr. Callen said.

Shared concerns

Other treatments currently being studied include bimekizumab for pustular psoriasis of the palms and soles, nemolizumab for prurigo nodularis, dupilumab for bullous pemphigoid, and mogamulizimab for cutaneous T-cell lymphoma.

The session will also feature a discussion of these treatments and others for multiple conditions, including:

- Blistering diseases
- Chronic urticaria
- Cutaneous T-cell lymphoma
- Hidradenitis
- Itching
- Pustular psoriasis

Dr. Callen, working with Michel F. Gilliet, MD, the European Academy of Dermatology and Venereology (EADV) representative, said these topics were selected because they are relevant in both Europe and the United States.

"But our approaches to evaluation and management might differ," Dr. Callen said. "There are excellent researchers on both sides of the Atlantic, and we specifically selected these topics as they have new options for therapy that are currently approved or will likely be approved in the near future."

A good fit

Dr. Callen said the AAD has always worked closely with its European counterpart, the EADV, to facilitate the exchange of ideas and research between European and American dermatologists. In fact, that partnership dates back to the formation of the EADV in 1987.

"When [the EADV] was formed, it based its annual meeting format largely on the use of the format of the AAD's Annual Meeting," Dr. Callen said.

In the spirit of cooperation, Dr. Callen said the AAD suggested having a joint session with the two organizations at each other's meetings to better help each association's members understand what was going on across the pond and gain new perspectives on various conditions they were seeing.

"Initially, the AAD session was held during the AAD's summer meeting, but in the last five or so years, the AAD session was moved to the Annual Meeting," Dr. Callen said. "Each organization has a member or committee that suggests three speakers annually for each session after assessing what appears to be the hot topics."

Other topics and speakers at tomorrow's globally inspired session include a lecture on chronic spontaneous urticaria; pruritus by Shawn Kwatra, MD, FAAD; hidradenitis suppurativa by Robert Micheletti, MD, FAAD; a presentation on cutaneous T-cell lymphoma; immunobullous diseases by John Joseph Zone, MD, FAAD; and pustular psoriasis by Jonathan Barker, MD. ●

HAPPENING TODAY

F084 – Boards and Beyond
1-3 p.m. | Sunday, March 10
Room 5B

Help with your boards and so much more

Boards and Beyond returns for exam prep and career guidance.

Morgan Murphrey, MD, MS

Ready for what's beyond residency? Take the time to prepare and learn from others during Sunday's session, F084 – Boards and Beyond. The session was so popular in 2023, it's returning for the 2024 AAD Annual Meeting.

Morgan Murphrey, MD, MS, will lead a panel of speakers who have forged unique paths in dermatology and are poised to share practical insights. Speakers represent dermatology in academics, private practice, and more. These are individuals who know that most residents and early-career dermatologists often report feeling inadequately prepared for the non-dermatologic aspects of medical practice, Dr. Murphrey said.

"The focus of dermatology residency training is understanding the skin, which is a large task in and of itself. Residents typically work in academic settings, where clinics have extra time built in for learning and discussion. There is typically additional time set aside for didactics or research pursuits," she said. "However, residents do not typically experience the business or administrative side of dermatology."

Feeling unprepared

Some residents, for example, do not have exposure to coding and reimbursement. And because residency is typically associated with a university system, many residents have little experience with other practice settings, such as private practice. These factors result in residents and early-career dermatologists who may not have adequate preparation for the non-academic aspects of medical practice, Dr. Murphrey said.

This session will briefly review the style and structure of the board exam, as well as relevant post-residency requirements (i.e., maintenance of certification requirements).

Participants will have an opportunity for a panel-like discussion with the speakers during the last 20 minutes of the session.

Getting the basics

The session is designed to prepare residents for the format of the American Board of Dermatology Board Examination, explore career and alternative career paths in dermatology, and provide tips and tricks for considering post-residency plans and early-career advice.

"Dermatology Board Examination is a day-long exam, which can be taken at a testing center or online, similar to the CORE exams. The test is broken into four blocks of 50 questions. Each block is allotted 94 minutes, and there are breaks during the exam. The questions are multiple choice," Dr. Murphrey said.

Additionally, she said post-residency certification is done through the CertLink program. Each quarter, residents receive six core dermatology questions, and three elective questions based on the topic of their choosing. They also receive four article-based questions, typically based on two articles. Test-takers are given 10 minutes per question, and can reattempt incorrect questions in subsequent quarters, Dr. Murphrey said. This differs from the older re-certification exam, which was required every 10 years.

Where will your career take you?

Residents and early-career dermatologists have employment choices in many diverse areas. Some professionals may be more interested and better suited in private practice or academics, where others migrate to serving patients in rural areas.

"For many dermatologists, there are opportunities to find a 'niche' or further area of interest, and build their practice around that specifically," Dr. Murphrey said. "For example, some dermatologists focus on hair and hair loss, others on pediatric patients, oncodermatology, melanoma, and pigmented lesions. Some dermatologists primarily practice in a research setting, and others work in industry...the list goes on. Our session will aim to give you a better sense of the various avenues of dermatology that can be explored."

Ultimately, Dr. Murphrey said, the session's goal is to offer a roadmap for those who are approaching their final training examination. It is meant to help residents and early-career dermatologists who are seeking inspiration and advice about their dermatology journey.

"As a dermatology resident or fellow, the post-training career hunt can be daunting. Entering our own paths may feel overwhelming. The goal of this session is to share experiences and offer insight for those who are considering how best to approach their future career," she said. ●

To serve and protect

Healthy skin barrier is essential in the fight against disease.

Jack L. Arbiser, MD, PhD, FAAD, dermatologist with Metroderm/ United Derm Partners in Atlanta

Skin. It's not only the body's largest organ, but it also serves as an important barrier to infection and disease. Protecting that barrier from damage and disruption requires a keen awareness of a multitude of molecular and immunological signaling pathways.

According to Jack L. Arbiser, MD, PhD, FAAD, a dermatologist with Metroderm/ United Derm Partners in Atlanta, careful attention to maintaining the skin's barrier function can guard against specific skin conditions such as atopic dermatitis, psoriasis, or other related issues. Dr. Arbiser unraveled the complexities of the skin barrier — the human shield against disease — during yesterday's session, S039 – Understanding the Skin Barrier.

"The human body is constantly surrounded by a mixture of beneficial and pathogenic bacteria, fungi, and viruses. Given the opportunity, the bacteria will try to invade the body and reach the blood stream," Dr. Arbiser said. "The skin barrier is both a physical barrier, like a suit of armor, and a chemical barrier. The chemical barrier signals immediately that the barrier has been breached and starts beneficial inflammation. In normal skin, inflammation is decreased when the threat is gone."

Barrier breach

Research has shown how disruption of the skin barrier can lead to inflammatory disorders, and how an intact skin barrier results in resolution of inflammation, he said. A healthy skin barrier includes proper maintenance of the acid mantle and appropriate levels of ceramides.

"Three factors are required for barrier function," Dr. Arbiser said. "The first is extracellular acid, which decreases inflammation as well as kills pathogenic staph and strep. Mitochondria are required for optimal production of skin structural proteins and antimicrobial peptides. Ceramides are the waxy lipids that waterproof the skin barrier and can be rapidly converted to pro-inflammatory sphingosine-1 phosphate to signal inflammation."

Although acute inflammation is necessary to fight off immediate threats, "sometimes the body does not turn off the inflammation or is signaling that it is being attacked when it is not," Dr. Arbiser said.

"This underlies chronic inflammation, which is bad," he said. "Similarly, mutations are happening in the skin all the time. For example, normally, the skin produces an inflammatory factor called IL-12 at a low level to harness the immune system to get rid of mutant cells. When the barrier is broken, IL-12 is diminished, allowing neoplastic cells to proliferate."

As part of the session, Dr. Arbiser reviewed the development of compounds that could target signaling pathways to provide more effective relief for patients. That review included looking at key factors mediating skin barrier regulation and inflammation, including skin acidity, interleukins, nuclear factor kappa B, and sirtuin 3. ●

Rubbing elbows

Attendees networked with more than 40 employers at Friday's AAD Career Networking Event at the Marriott Marquis San Diego Marina. The high-energy event gave dermatology job-seekers and soon-to-be graduates the opportunity to network with potential employers and dermatologists from all over the country.

NOW AVAILABLE!

Actor portrayal

ZORYVE®
(roflumilast) topical foam, 0.3%

DOWN TO AGE 9

Effectively control seborrheic dermatitis and simplify treatment with a steroid-free foam.[1]

One foam. Once a day. Anywhere.[1]

SebDone.

DRAMATIC 77% IGA SUCCESS AT WEEK 8[1,2]

Trial 203 and STRATUM studies evaluated ZORYVE (n=458) vs vehicle (n=225) once daily for 8 weeks in patients with seborrheic dermatitis. The primary endpoint was IGA Success at Week 8, defined as a score of *Clear* (0) or *Almost Clear* (1) and a ≥2-grade improvement from baseline.

ZORYVE is for topical use only and not for ophthalmic, oral, or intravaginal use.[1]

IGA = Investigator Global Assessment

A 2023 Arcutis survey of 93 adults diagnosed with seborrheic dermatitis found that an average of 15 products (including over-the-counter, alternative, and prescription treatments) were reportedly used on a yearly basis.[2]

INDICATION

ZORYVE foam, 0.3%, is indicated for the treatment of seborrheic dermatitis in adult and pediatric patients 9 years of age and older.

IMPORTANT SAFETY INFORMATION

ZORYVE is contraindicated in patients with moderate to severe liver impairment (Child-Pugh B or C).

Flammability: The propellants in ZORYVE are flammable. Avoid fire, flame, and smoking during and immediately following application.

The most common adverse reactions (≥1%) include nasopharyngitis (1.5%), nausea (1.3%), and headache (1.1%).

Please see brief summary of full Prescribing Information for ZORYVE foam on the following page.

See the results at zoryvehcp.com/foam

References: 1. ZORYVE® foam. Prescribing information. Arcutis Biotherapeutics, Inc; 2023.
2. Data on File. Arcutis Biotherapeutics, Inc.

ARCUTIS® BIOTHERAPEUTICS

US-COM-154-00125 01/24

Brief Summary of Prescribing Information for ZORYVE® (roflumilast) foam, 0.3%, for topical use. See package insert for full Prescribing Information.

INDICATIONS AND USAGE

ZORYVE foam, 0.3%, is indicated for the treatment of seborrheic dermatitis in adult and pediatric patients 9 years of age and older.

DOSAGE AND ADMINISTRATION

Shake can prior to each use. Apply a thin layer of ZORYVE foam, 0.3%, once daily to affected areas on skin and/or scalp when they are not wet. Rub in completely.

Wash hands after application.

Avoid fire, flame, and smoking during and immediately following application.

ZORYVE foam, 0.3%, is for topical use only and not for ophthalmic, oral, or intravaginal use.

CONTRAINDICATIONS

ZORYVE foam, 0.3%, is contraindicated in patients with moderate to severe liver impairment (Child-Pugh B or C).

WARNINGS AND PRECAUTIONS

Flammability

The propellants in ZORYVE foam, 0.3%, are flammable. Avoid fire, flame, and smoking during and immediately following application.

ADVERSE REACTIONS

Clinical Trials Experience

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

In two multicenter, randomized, double-blind, vehicle-controlled trials (Trial 203 and STRATUM), 683 adult and pediatric subjects 9 years of age or older with seborrheic dermatitis were treated with ZORYVE foam, 0.3%, or vehicle foam once daily for 8 weeks.

The combined trial population was 79% White, 11% Black, and 5% Asian; for ethnicity, 79% identified as non-Hispanic/Latino and 21% identified as Hispanic/Latino. Fifty percent (50%) were male and 50% were female. The median age was 41 years (range 9 to 87 years). The median body surface area (BSA) affected was 2.5%.

Table 1 presents adverse reactions that occurred in at least 1% of subjects treated with ZORYVE foam, 0.3%.

Table 1. Adverse Reactions Reported in ≥1% of Subjects with Seborrheic Dermatitis Treated with ZORYVE Foam, 0.3%, for 8 Weeks in Trial 203 and Trial STRATUM

Adverse Reaction	ZORYVE foam, 0.3% (N=458) n (%)	Vehicle foam (N=225) n (%)
Nasopharyngitis	7 (1.5)	1 (0.4)
Nausea	6 (1.3)	0 (0)
Headache	5 (1.1)	0 (0)

The following additional adverse reactions were reported in fewer than 1% of subjects treated with ZORYVE foam, 0.3%: diarrhea and insomnia.

In 408 subjects who continued treatment with ZORYVE foam, 0.3%, for up to 24 to 52 weeks in an open-label, long-term trial, the adverse reaction profile was consistent with that observed in vehicle-controlled trials.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

There are insufficient data available on the use of ZORYVE foam, 0.3%, in pregnant women to inform a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. In animal reproduction studies, roflumilast administered orally to pregnant rats and rabbits during the period of organogenesis produced no fetal structural abnormalities at doses up to 30 and 26 times the maximum recommended human dose (MRHD), respectively. Roflumilast induced post-implantation loss in rats at oral doses greater than or equal to 10 times the MRHD. Roflumilast induced stillbirth and decreased pup viability in mice at oral doses 16 and 49 times the MRHD, respectively. Roflumilast has been shown to adversely affect pup post-natal development when dams were treated with an oral dose 49 times the MRHD during pregnancy and lactation periods in mice.

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% to 4% and 15% to 20%, respectively.

Clinical Considerations

Labor and delivery

Avoid using ZORYVE foam, 0.3%, during labor and delivery. There are no human studies that have investigated effects of ZORYVE foam, 0.3%, on preterm labor or labor at term; however, animal studies showed that oral roflumilast disrupted the labor and delivery process in mice.

Data

Animal data

In an embryo-fetal development study, pregnant rats were dosed orally during the period of organogenesis with up to 1.8 mg/kg/day roflumilast (30 times the MRHD on a mg/m^2 basis). No evidence of structural abnormalities or effects on survival rates were observed. Roflumilast did not affect embryo-fetal development at a maternal oral dose of 0.2 mg/kg/day (3 times the MRHD on a mg/m^2 basis).

In a fertility and embryo-fetal development study, male rats were dosed orally with up to 1.8 mg/kg/day roflumilast for 10 weeks and females for 2 weeks prior to pairing and throughout the organogenesis period. Roflumilast induced pre- and post-implantation loss at maternal oral doses greater than or equal to 0.6 mg/kg/day (10 times the MRHD on a mg/m^2 basis). Roflumilast did not cause fetal structural abnormalities at maternal oral doses up to 1.8 mg/kg/day (29 times the MRHD on a mg/m^2 basis).

In an embryo-fetal development study in rabbits, pregnant does were dosed orally with 0.8 mg/kg/day roflumilast during the period of organogenesis. Roflumilast did not cause fetal structural abnormalities at the maternal oral doses of 0.8 mg/kg/day (26 times the MRHD on a mg/m^2 basis).

In pre- and post-natal developmental studies in mice, dams were dosed orally with up to 12 mg/kg/day roflumilast during the period of organogenesis and lactation. Roflumilast induced stillbirth and decreased pup viability at maternal oral doses greater than 2 mg/kg/day and 6 mg/kg/day, respectively (16 and 49 times the MRHD on a mg/m^2 basis, respectively). Roflumilast induced delivery retardation in pregnant mice at maternal oral doses greater than 2 mg/kg/day (16 times the MRHD on a mg/m^2 basis). Roflumilast decreased pup rearing frequencies at a maternal oral dose of 6 mg/kg/day during pregnancy and lactation (49 times the MRHD on a mg/m^2 basis). Roflumilast also decreased survival and forelimb grip reflex and delayed pinna detachment in mouse pups at a maternal oral dose of 12 mg/kg/day (97 times the MRHD on a mg/m^2 basis).

Lactation

Risk Summary

There are no data on the presence of roflumilast or its metabolite in human milk, the effects on the breastfed infant, or the effects on milk production.

Roflumilast and/or its metabolites are excreted into the milk of lactating rats. When a drug is present in animal milk, it is likely that the drug will be present in human milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for ZORYVE foam, 0.3%, and any potential adverse effects on the breastfed infant from ZORYVE foam, 0.3%, or from the underlying maternal condition.

Clinical Considerations

To minimize potential exposure to the breastfed infant via breast milk, use ZORYVE foam, 0.3%, on the smallest area of skin and for the shortest duration possible while breastfeeding. To avoid direct infant exposure, advise breastfeeding women not to apply ZORYVE foam, 0.3%, directly to the nipple or areola. If applied to the patient's chest, avoid exposure via direct contact with the infant's skin.

Data

Animal data

Roflumilast and/or its metabolite concentrations measured 8 hours after an oral dose of 1 mg/kg given to lactating rats were 0.32 and 0.02 mcg/g in the milk and pup liver, respectively.

Pediatric Use

The safety and effectiveness of ZORYVE foam, 0.3%, for the treatment of seborrheic dermatitis have been established in pediatric patients 9 years of age and older. Use of ZORYVE foam, 0.3%, in this age group is supported by data from two 8-week, vehicle-controlled trials which included 32 pediatric subjects 9 to 17 years of age, of whom 17 received ZORYVE foam, 0.3%, and from open-label trials of up to 52 weeks which included 23 pediatric subjects treated with ZORYVE foam, 0.3%. The adverse reaction profile was consistent with that observed in adults.

The safety and effectiveness of ZORYVE foam, 0.3%, in pediatric patients below the age of 9 years have not been established.

Geriatric Use

Of the 683 subjects with seborrheic dermatitis exposed to ZORYVE foam, 0.3%, or vehicle for up to 8 weeks in the controlled clinical trials, 98 (14%) were 65 years of age or older, and 33 (5%) were 75 years of age or older. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

Hepatic Impairment

Oral roflumilast 250 mcg once daily for 14 days was studied in subjects with hepatic impairment. The systemic exposure of roflumilast and roflumilast N-oxide were increased in subjects with moderate (Child-Pugh B) hepatic impairment. ZORYVE foam, 0.3%, is contraindicated in patients with moderate to severe liver impairment (Child-Pugh B or C). No dosage adjustment is needed in patients with mild (Child-Pugh A) hepatic impairment.

PATIENT COUNSELING INFORMATION

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

Flammability

Because the propellants in ZORYVE foam, 0.3%, are flammable, instruct the patient to avoid fire, flame, and smoking during and immediately following application.

Lactation

Advise patients to use ZORYVE foam, 0.3%, on the smallest area of skin and for the shortest duration possible while breastfeeding. Instruct patients who are breastfeeding not to apply ZORYVE foam, 0.3%, directly to the nipple or areola to avoid direct infant exposure. Instruct patients to avoid inadvertent contact of treated areas with infant skin.

FOR PLAQUE PSORIASIS
AGE 6+

ZORYVE®
(roflumilast) cream 0.3%

Effective. Everywhere. Easy.[1]

A once-daily, steroid-free cream with the **power to clear elbows and knees**, and the **gentleness for face and folds**.[1,2]

Actor portrayal

In DERMIS-1 and DERMIS-2, ~40% of patients achieved IGA Success and ~70% of patients achieved I-IGA Success at Week 8.[1]

DERMIS-1 and DERMIS-2 were identical Phase 3 randomized, parallel, double-blind, vehicle-controlled, multicenter studies that evaluated ZORYVE over 8 weeks as a once-daily, topical treatment for plaque psoriasis. Subjects (N=881) were randomized 2:1 to receive ZORYVE cream 0.3% (n=576) or vehicle (n=305) applied once daily for 8 weeks. Eligibility criteria included a diagnosis of mild, moderate, or severe plaque psoriasis and an affected BSA of 2% to 20%. The primary endpoint was IGA Success at Week 8 and a key secondary endpoint was I-IGA Success at Week 8.[1]

IGA Success and I-IGA Success were defined as a score of *Clear* (0) or *Almost Clear* (1) and a ≥2-grade improvement from baseline.[1,2]

ZORYVE is for topical use only and not for ophthalmic, oral, or intravaginal use.[1]

BSA = Body Surface Area, IGA = Investigator Global Assessment, I-IGA = Intertriginous-IGA

INDICATION

ZORYVE cream is indicated for topical treatment of plaque psoriasis, including intertriginous areas, in patients 6 years of age and older.

IMPORTANT SAFETY INFORMATION

ZORYVE is contraindicated in patients with moderate to severe liver impairment (Child-Pugh B or C).

The most common adverse reactions (≥1%) include diarrhea (3.1%), headache (2.4%), insomnia (1.4%), nausea (1.2%), application site pain (1.0%), upper respiratory tract infection (1.0%), and urinary tract infection (1.0%).

Please see brief summary of full Prescribing Information for ZORYVE cream on the following page.

See the results at zoryvehcp.com/cream

References: 1. ZORVYE® cream. Prescribing information. Arcutis Biotherapeutics, Inc; 2023.
2. Data on File. Arcutis Biotherapeutics, Inc.

ARCUTIS® BIOTHERAPEUTICS

US-COM-151-00311 01/24

Brief Summary of Prescribing Information for ZORYVE® (roflumilast) cream, for topical use. See package insert for full Prescribing Information.

INDICATIONS AND USAGE

ZORYVE cream is indicated for topical treatment of plaque psoriasis, including intertriginous areas, in patients 6 years of age and older.

DOSAGE AND ADMINISTRATION

Apply ZORYVE cream to affected areas once daily and rub in completely. Wash hands after application, unless ZORYVE cream is for treatment of the hands.

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

CONTRAINDICATIONS

ZORYVE cream is contraindicated in patients with moderate to severe liver impairment (Child-Pugh B or C).

ADVERSE REACTIONS

Clinical Trials Experience

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

In two multicenter, randomized, double-blind, vehicle-controlled trials (DERMIS-1 and DERMIS-2), 881 adult and pediatric subjects 6 years of age or older with plaque psoriasis were treated with ZORYVE cream or vehicle topically once daily for 8 weeks.

The median age was 47 years (range 6 to 88). The majority of the subjects were male (64%) and White (82%). The median body surface area (BSA) affected was 5.5% (range 2% to 20%). The proportion of subjects who discontinued treatment due to an adverse reaction was 1.0% for subjects treated with ZORYVE cream and 1.3% for subjects treated with vehicle cream. The most common adverse reaction that led to discontinuation of ZORYVE cream was application site urticaria (0.3%).

Table 1 presents adverse reactions that occurred in at least 1% of subjects treated with ZORYVE cream, and for which the rate exceeded the rate for vehicle cream.

Table 1. Adverse Reactions Reported in ≥1% of Subjects with Plaque Psoriasis Treated with ZORYVE Cream (and More Frequently than Vehicle Cream) for 8 Weeks in Trials DERMIS-1 and DERMIS-2

Adverse Reaction	ZORYVE Cream (N=576) n (%)	Vehicle Cream (N=305) n (%)
Diarrhea	18 (3.1)	0 (0.0)
Headache	14 (2.4)	3 (1.0)
Insomnia	8 (1.4)	2 (0.7)
Nausea	7 (1.2)	1 (0.3)
Application site pain	6 (1.0)	1 (0.3)
Upper respiratory tract infection	6 (1.0)	1 (0.3)
Urinary tract infection	6 (1.0)	2 (0.7)

In 594 subjects who continued treatment with ZORYVE cream for up to 64 weeks in open-label extension trials, the adverse reaction profile was consistent with that observed in vehicle-controlled trials.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

There are insufficient data available on the use of ZORYVE cream in pregnant women to inform a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. In animal reproduction studies, roflumilast administered orally to pregnant rats and rabbits during the period of organogenesis produced no fetal structural abnormalities at doses up to 36 and 31 times the maximum recommended human dose (MRHD), respectively. Roflumilast induced post-implantation loss in rats at oral doses greater than or equal to 12 times the MRHD. Roflumilast induced stillbirth and decreased pup viability in mice at oral doses 19 and 59 times the MRHD, respectively. Roflumilast has been shown to adversely affect pup post-natal development when dams were treated with an oral dose 59 times the MRHD during pregnancy and lactation periods in mice.

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% to 4% and 15% to 20%, respectively.

Clinical Considerations

Labor and delivery

Avoid using ZORYVE cream during labor and delivery. There are no human studies that have investigated effects of ZORYVE cream on preterm labor or labor at term; however, animal studies showed that oral roflumilast disrupted the labor and delivery process in mice.

Data

Animal data

In an embryo-fetal development study, pregnant rats were dosed orally during the period of organogenesis with up to 1.8 mg/kg/day roflumilast (36 times the MRHD on a mg/m^2 basis). No evidence of structural abnormalities or effects on survival rates were observed. Roflumilast did not affect embryo-fetal development at a maternal oral dose of 0.2 mg/kg/day (4 times the MRHD on a mg/m^2 basis).

In a fertility and embryo-fetal development study, male rats were dosed orally with up to 1.8 mg/kg/day roflumilast for 10 weeks and females for 2 weeks prior to pairing and throughout the organogenesis period. Roflumilast induced pre- and post-implantation loss at maternal oral doses greater than or equal to 0.6 mg/kg/day (12 times the MRHD on a mg/m^2 basis). Roflumilast did not cause fetal structural abnormalities at maternal oral doses up to 1.8 mg/kg/day (35 times the MRHD on a mg/m^2 basis).

In an embryo-fetal development study in rabbits, pregnant does were dosed orally with 0.8 mg/kg/day roflumilast during the period of organogenesis. Roflumilast did not cause fetal structural abnormalities at the maternal oral doses of 0.8 mg/kg/day (31 times the MRHD on a mg/m^2 basis).

In pre- and post-natal developmental studies in mice, dams were dosed orally with up to 12 mg/kg/day roflumilast during the period of organogenesis and lactation. Roflumilast induced stillbirth and decreased pup viability at maternal oral doses greater than 2 mg/kg/day and 6 mg/kg/day, respectively (19 and 59 times the MRHD on a mg/m^2 basis, respectively). Roflumilast induced delivery retardation in pregnant mice at maternal oral doses greater than 2 mg/kg/day (19 times the MRHD on a mg/m^2 basis). Roflumilast decreased pup rearing frequencies at a maternal oral dose of 6 mg/kg/day during pregnancy and lactation (59 times the MRHD on a mg/m^2 basis). Roflumilast also decreased survival and forelimb grip reflex and delayed pinna detachment in mouse pups at a maternal oral dose of 12 mg/kg/day (116 times the MRHD on a mg/m^2 basis).

Lactation

Risk Summary

There are no data on the presence of roflumilast or its metabolite in human milk, the effects on the breastfed infant, or the effects on milk production.

Roflumilast and/or its metabolites are excreted into the milk of lactating rats. When a drug is present in animal milk, it is likely that the drug will present in human milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for ZORYVE cream and any potential adverse effects on the breastfed infant from ZORYVE cream or from the underlying maternal condition.

Clinical Considerations

To minimize potential exposure to the breastfed infant via breast milk, use ZORYVE cream on the smallest area of skin and for the shortest duration possible while breastfeeding. To avoid direct infant exposure, advise breastfeeding women not to apply ZORYVE cream directly to the nipple or areola. If applied to the patient's chest, avoid exposure via direct contact with the infant's skin.

Data

Animal data

Roflumilast and/or its metabolite concentrations measured 8 hours after an oral dose of 1 mg/kg given to lactating rats were 0.32 and 0.02 mcg/g in the milk and pup liver, respectively.

Pediatric Use

The safety and effectiveness of ZORYVE cream for the treatment of plaque psoriasis have been established in pediatric patients 6 years of age and older. Use of ZORYVE cream in pediatric patients 6 to less than 18 years of age is supported by data from two 8-week, vehicle-controlled safety and efficacy trials which included 18 pediatric subjects 6 to 17 years of age, of whom 11 received ZORYVE cream. Use of ZORYVE cream in pediatric patients 12 to 17 years of age is also supported by data from open-label trials of 2 and 24 weeks duration which included 18 pediatric subjects 12 to 17 years of age treated with ZORYVE cream. Use of ZORYVE cream in pediatric patients 6 to less than 12 years of age is also supported by data from one 4-week, open-label, safety and pharmacokinetic (PK) study which included 20 pediatric subjects 6 to less than 12 years of age. The adverse reaction profile in subjects 6 to less than 18 years of age was consistent with that observed in adults.

The safety and effectiveness of ZORYVE cream in pediatric patients below the age of 6 years have not been established.

Geriatric Use

Of the 881 subjects with psoriasis exposed to ZORYVE cream or vehicle for up to 8 weeks in 2 controlled clinical trials, 106 were 65 years of age or older. No overall differences in safety or effectiveness were observed between these subjects and younger subjects. Other reported clinical experience has not identified differences in responses between the geriatric and younger patients, but greater sensitivity of some older individuals cannot be ruled out. Based on available data for roflumilast, no adjustment of dosage in geriatric patients is warranted.

Hepatic Impairment

Oral roflumilast 250 mcg once daily for 14 days was studied in subjects with hepatic impairment. The systemic exposure of roflumilast and roflumilast N-oxide were increased in subjects with moderate (Child-Pugh B) hepatic impairment. ZORYVE cream is contraindicated in patients with moderate to severe liver impairment (Child-Pugh B or C). No dosage adjustment is needed in patients with mild (Child-Pugh A) hepatic impairment.

PATIENT COUNSELING INFORMATION

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

Lactation

Advise patients to use ZORYVE cream on the smallest area of skin and for the shortest duration possible while breastfeeding. Instruct patients who are breastfeeding not to apply ZORYVE cream directly to the nipple and areola to avoid direct infant exposure. Instruct patients to avoid inadvertent contact of treated areas with infant skin.

High-tech hair growth

Non-drug options are flourishing.

Technology to the rescue. Those words may offer hope to countless individuals diagnosed with alopecia. With a rise in emerging technologies for the management of the condition, Saturday's session, U040 – Technological Advancements for the Management of Complex Alopecias, served as the backdrop for a robust discussion of what's new and what's to come.

More than medication

Session director Ronda S. Farah, MD, FAAD, associate professor of dermatology at the University of Minnesota Medical School in Minneapolis, explored the role that certain diverse technologies, such as artificial intelligence (AI), platelet rich plasma (PRP), photobiomodulation (low-level light therapy), hydradermabrasion, hair transplantation, and research in regenerative medicine, play in growing hair and outpacing drug therapy.

"Hair technologies are flourishing. Scalp health is of great interest to consumers and physicians. Dermatologists are taking this to the next level by studying the microbiome," Dr. Farah said. "Also, we are so excited to be working with the industry to launch new hair lasers. In the past, we have worked with photobiomodulation and found in our data that the combs work well in men and women."

From left: Marc R. Avram, MD, FAAD; Ronda S. Farah, MD, FAAD

Transplant solutions

During the session, Marc R. Avram, MD, FAAD, clinical professor of dermatology at Weill Cornell Medical College in New York, discussed the benefits of hair transplantation. According to Dr. Avram, hair transplantation produces consistently natural-appearing hair for women and men. He credits that to FUT and FUE — two state-of-the-art techniques used to harvest hair from the donor region in the posterior scalp of women and men.

During the harvesting consult, the dermatologist will determine which procedure is best. However, both create a natural look, and require a team of skilled surgical assistants.

Additionally, Dr. Avram said long-term medical therapy is important to achieve maximum density from the procedure.

"While a transplant will add density and more hair, it will not stop underlying thinning," he said. "The majority of our hair transplant patients are on long-term medical therapy such as oral finasteride or minoxidil, PRP, or topical minoxidil and finasteride."

According to Dr. Avram, hair transplantation can be performed to restore eyebrows as well as repair lost hair from scarring alopecia.

A dream come true

Although most of the session focused on technology, Dr. Farah discussed the integration of oral minoxidil as part of a treatment plan, as it can be beneficial.

"In the last few years our experience with minoxidil has soared. We are excited to share our dosing and starting criteria," she said. "Hair loss medicine and technologies are rapidly evolving. Hair loss is no longer a visit with few tools. It's a visit that the dermatologist will find fulfilling for everyone. We have so much to offer our patients." ●

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