AN INDEPENDENT SUPPLEMENT BY MEDIAPLANET TO USA TODAY



MEDIA PLANET

# HEALTHY SKIN

3 TIPS FOR A GREAT COMPLEXION

PHOTO CREDIT: NITSAN TAL PHOTOGRAPHY AND MAKEUP: ALISON RAFAELLE COSMETICS

## BEAUTY BEYOND THE SURFACE

**Emme, plus-size model and wellness advocate,** prepares you to put your best face forward

CHALLENGES

**Skin disease** is more prevalent than anyone ever imagined and carries with it serious medical consequences.

# Let your skin reflect the beauty within you

At any given time, one in every three people in the United States suffers from a skin disease. The American Academy of Dermatology Association and the Society for Investigative Dermatology commissioned a study by the Lewin Group to quantify the burden of skin disease. This study shows that skin disease is more prevalent than anyone ever imagined—and carries serious medical and financial consequences. This study analyzed 22 skin diseases and found that the direct costs (prescription drugs, hospital and doctor visits, nursing care and over the counter products) totaled $29.1 billion. The total indirect costs associated with lost productivity of not being able to work and taking time for doctors' visits totaled $10.2 billion.

Cost is not the only issue with skin diseases. Since most skin diseases are visible, there are psychological issues that may severely affect quality of life. Picture the adolescent that has severe acne, the young man who no longer feels comfortable going to the gym to work out because of skin rashes, the child who has deformities and others that have chronic blistering or are unable to sweat.

This supplement highlights a few of the more common skin diseases: rosacea, eczema and skin cancer, as well as the importance of loving the skin you're in. There are thousands of other skin diseases, some that are relatively easy to treat and curable. Some are life threatening. Others are very rare, have few treatment options and patients will live with them their entire life.

## You're not alone

Many patients with skin disease may think they are the only ones affected and feel very alone if they don't know anyone else with their disease. There is support available in many different ways through patient advocacy groups. Many of the members of the Coalition of Skin Diseases have patient education meetings, online support groups and disease specific information on their websites. Educating yourself will give you more information about treatments available and suggestions about living with your disease. Their websites will give you additional resources that may be helpful.

*The Coalition of Skin Diseases (CSD) is a voluntary coalition of patient advocacy groups addressing the needs and concerns of millions of people whose lives are affected by skin disease. For a list of members of the Coalition of Skin Diseases and how to contact them for more information, go to www.coalitionofskindiseases.org.*

"Picture the adolescent that has severe acne, the young man who no longer feels comfortable going to the gym, the child that has deformities …"

**Judy Jones**
President, Coalition of Skin Diseases

WE RECOMMEND

**Check out the interview** with plus-size model and health, wellness advocate, Emme.

PAGE 9

**A far too common cancer** p. 4
Learn all about skin cancer prevention from the Skin Cancer Foundation and Dr. Perry Robins.

MEDIA PLANET

HEALTHY SKIN
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# A Call To Action For Healthy Skin

The Sturge-Weber Foundation

Fiona is one of over 10,000 people with a port wine birthmark that results in Sturge-Weber syndrome which affects the eye, brain and skin causing glaucoma, seizures and other secondary health issues. Since 1987, The Sturge-Weber Foundation improves the quality of life for children and adults like Fiona around the world and for all people with a birthmark. We participate in collaborative education, advocacy and translational research to promote medical management and to identify the cause. www.sturge-weber.org
**swf@sturge-weber.org • 1-800-627-5482**

## Cutaneous Lymphoma Foundation

Do you have a persistent rash or abnormal skin lesions? Cutaneous T-cell lymphoma (CTCL) is a rare and treatable form of blood cancer that typically presents first as a rash, lesion or plaque on the skin. Since 1998, the Cutaneous Lymphoma Foundation has been helping patients, caregivers and physicians improve CTCL diagnosis and treatment while offering a wide range of programs, support and resources. A stubborn skin irritation may turn out to be CTCL. Visit www.clfoundation.org and talk to your doctor to learn more about CTCL, its symptoms and how to get help.
**www.clfoundation.org • 248.644.9014**

## Pachyonychia Congenita Project

Pachyonychia Congenita (PC) is a ultra rare genetic skin disorder characterized by painful calluses on the soles of the feet, thickened nails and cysts. PC Project seeks treatments and a cure for this debilitating disorder through (a) an international patient registry (IPCRR) which provides free consultations and genetic testing and (b) sponsorship of the International PC Consortium (IPCC) which includes both scientists and physicians. PC Project initiated the first siRNA clinical trial for skin.
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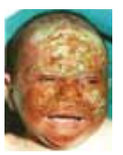
**www.uvsunsense.com**

## Xeroderma Pigmentosum Family Support Group



The XP Family Support Group is dedicated to improving the quality of life of those affected with Xeroderma Pigmentosum through education and support services, researching effective treatments, and ultimately finding a cure. Xeroderma Pigmentosum (or XP) is a rare inherited disease affecting both males and females. It causes a person to be extremely sensitive to the damaging effects of ultraviolet radiation. Undiagnosed and untreated, XP can lead to the early onset of skin cancer and blindness. In addition, approximately 20% of people with XP also develop progressive neurological disease.
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INSIGHT

NEWS

## Know your facts for early prevention

**Skin cancer is the most common form of cancer in the United States. More than 3.5 million skin cancers in over two million people are diagnosed annually.**

Actinic keratosis is the most common precancer; it affects more than 58 million Americans. Approximately 65 percent of all squamous cell carcinomas arise in lesions that previously were diagnosed as actinic keratoses. In patients with a history of two or more skin cancers, 36 percent of basal cell carcinomas arise in lesions previously diagnosed as actinic keratoses.

Basal cell carcinoma (BCC) is the most common form of skin cancer; an estimated 2.8 million are diagnosed annually in the US. BCCs are rarely fatal, but can be highly disfiguring if allowed to grow.

Squamous cell carcinoma (SCC) is the second most common form of skin cancer. An estimated 700,000 cases are diagnosed each year in the US, resulting in approximately 2,500 deaths.

Credit: Skin Cancer Foundation

**Question:** Why is it imperative to check your skin frequently for signs of skin cancer?
**Answer:** If diagnosed early, it is one of the easiest cancers to treat.

TIP 1
DRINK WATER FOR GOOD SKIN HYDRATION

# A far too common cancer

Skin cancer is the most common of all cancers, afflicting more than two million Americans each year, a number that is rising rapidly. It is also one of the easiest cancers to treat successfully, if diagnosed early. When allowed to progress, however, skin cancer can result in disfigurement and even death.

That is why it is imperative to check your skin frequently for signs of skin cancer. Skin self-exams should be performed once a month, in addition to an annual full-body skin exam by your physician. A skin self-exam involves systematically examining your entire body for skin changes that could be warning signs of the most common skin cancers (basal and squamous cell carcinomas as well as melanoma, the deadliest form of skin cancer).

During your self-exam, note any changes in your skin, such as increases in size or changes in the shape of any growth, spot, sore, mole or lesion. If your skin shows any warning signs of skin cancer, consult your physician. Also be on the lookout for moles that appear after age 21. Any new skin growth, beauty mark, mole, brown spot, wound, or sore that doesn't heal can be cause for concern. For a complete self-exam how-to guide, visit www.SkinCancer.org/Self-Examination.

A self-exam should not replace an annual skin exam. Everyone should see a physician, preferably one who specializes in diseases of the skin, once a year, or more often if you have a history of skin cancer. If you do not have access to a dermatologist, look for skin cancer screenings in your area. The Skin Cancer Foundation's Road to Healthy Skin Tour, presented by AVEENO and Rite Aid, will begin its fourth year on the road next month. The Tour provides free skin cancer screenings and valuable information to thousands of people around the country. Over the past three years, 300 dermatologists have volunteered for the tour, collectively examining more than 10,000 patients in our fully equipped, customized RV. To find out if the Tour will be in your area, visit www.SkinCancer.org/Tour.

The risks of developing dangerous skin cancers can be dramatically and easily reduced through education, behavior modification, and early detection. Since its inception in 1979, The Skin Cancer Foundation has always recommended using a sunscreen with an SPF 15 or higher as one important part of a complete sun protection regimen. Sunscreen alone is not enough, however. Read our full list of skin cancer prevention tips below.

**Perry Robins, MD**
Professor Emeritus of Dermatology and former Chief of the Mohs Micrographic Surgery Unit, New York University Medical Center

"The risks of developing dangerous skin cancers can be dramatically and easily reduced through education, behavior modification and early detection."

### The Skin Cancer Foundation's prevention guidelines

- Seek the shade, especially between 10 AM and 4 PM.
- Do not burn.
- Avoid tanning and UV tanning booths.
- Cover up with clothing, including a broad-brimmed hat and UV-blocking sunglasses.
- Use a broad spectrum (UVA/UVB) sunscreen with an SPF of 15 or higher every day. For extended outdoor activity, use a water-resistant, broad spectrum (UVA/UVB) sunscreen with an SPF of 30 or higher.
- Apply one ounce (two tablespoons) of sunscreen to your entire body 30 minutes before going outside. Reapply every two hours or immediately after swimming or excessive sweating.
- Keep newborns out of the sun. Sunscreens should be used on babies over the age of six months.
- Examine your skin head-to-toe every month.
- See your physician every year for a professional skin exam.

**Founded in 1981, Dermatone® develops premium sunscreen formulations for optimal skin protection for the outdoor enthusiast.**

Our sunscreens provide protection from UVA radiation which causes photoaging and is linked to aggressive skin cancers. Dermatone's transparent zinc oxide formula with Z-Cote® blocks UVA as well as UVB and is invisible on the skin. You get the benefits of Zinc over chemical sunscreens. Zinc has 300 years of use with a remarkable safety record. Z-Cote is completely photostable, providing protection that lasts. Dermatone's formulas pass stringent testing for sweat and water proofing. Our sunscreen is recommended by Dermatologists and provides safe, effective skin protection for the outdoor enthusiast both in winter and summer. Dermatone's SPF 36 Z-Cote lotion is ideal for warmer weather. Dermatone SPF 30 Lips 'n Face protector tin is optimal for cold weather providing frostbite and windburn protection plus sunscreen. Dermatone is the official sunscreen of the U.S. Ski Team and U.S Snowboarding.

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NEWS

QUESTION & ANSWER

**Adelaide A. Hebert, MD**
Professor of Dermatology and Pediatrics, The University of Texas Health Sciences Center at Houston

**How do you get eczema and is it contagious?**

Eczema has a genetic basis. Our genes tell our skin how it will be made. Eczema is not contagious. Secondary bacterial infections in the skin can be contagious.

**How do you treat eczema and is there a cure?**

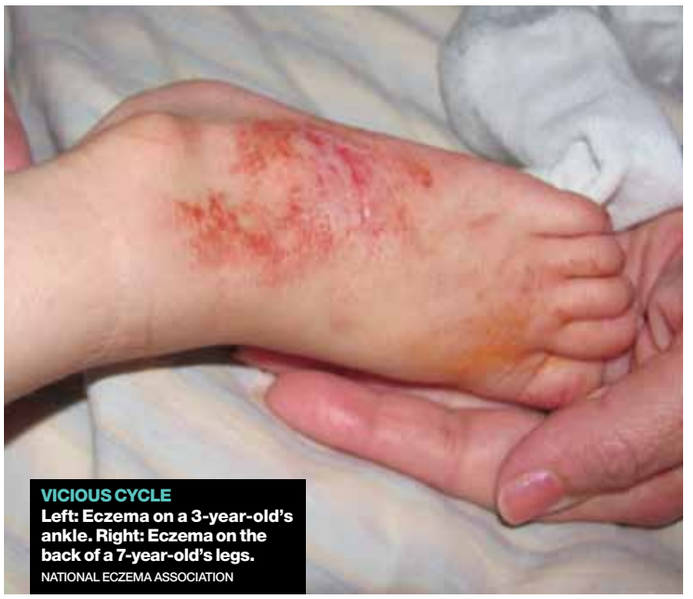
The most important means of treating eczema is with education about the condition itself. Learning the best methods for bathing, avoiding drying soaps, using lubrication and controlling itching are cornerstones of management. When infections develop, these should be treated appropriately.

**What are the signs and symptoms?**

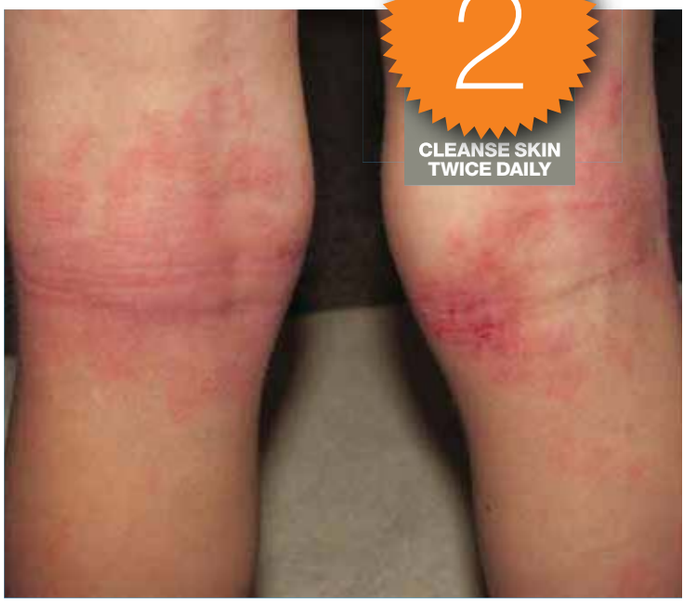
Eczema is characterized by dry, itchy skin that comes and goes over time. The patient affected with eczema may describe an "itch that rashes" as the itch will herald the onset of a flare of the dermatitis. Small children have red patches on the face and extremities while older children get thickened dry patches in front of the elbows and behind the knees.

**Is eczema biased to age, gender or race?**

All races and both genders may be affected. Most eczema patients have dermatitis within the first year of life. Up to 17 percent of school children in the U.S. have some form of eczema.
In countries where hygiene is poor, eczema prevalence is reduced. Parents are encouraged to see a dermatologist early on.



**VICIOUS CYCLE**
**Left: Eczema on a 3-year-old's ankle. Right: Eczema on the back of a 7-year-old's legs.**
NATIONAL ECZEMA ASSOCIATION



TIP 2
CLEANSE SKIN TWICE DAILY

# The maddening itch

The skin rash known as eczema can be maddening—enough to drive otherwise calm, sane people right up the wall. Long-lasting relief is possible, though.

Eczema is increasingly common. Between 15 and 20 percent of the population—some estimates are even higher—suffers from this irritating condition. It is especially common in children but occurs at all ages. Eczema is characterized by rough patches of inflamed skin that itch with a vengeance. Scratching just makes it itch more, creating an especially vicious cycle.

No one knows exactly what causes eczema. In some cases the inflammation is set off by an overzealous immune system. There seems to be a genetic component for some people, and some sufferers have skin that is just not very good at maintaining its barriers—keeping moisture in and irritants out, explains Peter Lio, MD, assistant professor of clinical dermatology and pediatrics Northwestern University School of Medicine.

"Between 15 and 20 percent of the population—some estimates are even higher—suffers from this irritating skin condition."

**Peter Lio, MD**
Assistant Professor of Clinical Dermatology and Pediatrics, Northwestern University School of Medicine

Many things can trigger an outbreak of eczema in those who are prone to it. Long hot baths or showers, sweating, harsh soaps or household cleansers, and wool fabrics are common triggers. Stress can also be a trigger.

## Put it to sleep

Though eczema cannot be cured, only managed, Lio says that is not as dismal as it sounds. "The coolest thing I have discovered is that when we get eczema under control with an aggressive, proactive approach, most patients go into something like a remission," he says. Breaking the cycle of itching, scratching, worse itching, more scratching, seems to send the condition into a quiet phase.

For those with mild outbreaks, this can often be accomplished by taking a few easy steps:

- Use a good moisturizer several times a day.
- Try not to scratch. When you feel the need to scratch, add moisturizer instead, Lio suggests.
- Use over the counter corticosteroids, if necessary, to control the inflammation and itching. Used as directed—during outbreaks, not daily—these medications are safe and effective.

## Wrapping it up

When these measures are not enough, doctors will often use a wet wrap. The effected area is thoroughly moisturized, then wrapped in damp bandages. This blocks out irritants and gives the skin a chance to absorb moisture. It also reduces itching and prevents scratching. Lio has found that wet wraps are often enough to send eczema into remission. But if that doesn't do the trick, prescription medications, such as stronger corticosteroids and immunomodulators are available. For more information please visit: www.nationaleczema.org.

**AVERY HURT**
editorial@mediaplanet.com

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- ✓ For patients 3 months or older
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**INDICATION & USAGE**
Desonate Gel is indicated for the treatment of mild to moderate atopic dermatitis in patients 3 months of age and older.

**IMPORTANT SAFETY INFORMATION**
As with other corticosteroids, therapy should be discontinued when control is achieved. Unless directed by a physician, the treated skin area should not be bandaged so as to be occlusive. Systemic absorption of topical corticosteroids, including Desonate Gel, has produced HPA axis suppression, for which pediatric patients are more susceptible.

In clinical trials, the most frequent adverse events included headache (2%), application site burning (1%), rash (1%), and application site pruritus (<1%). The safety of Desonate Gel has not been established beyond 4 weeks of use.

Desonate Gel is contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation.

Desonate Gel is for topical use only. Desonate Gel is not for ophthalmic, oral, or intravaginal use.

Desonate Gel is not indicated for the treatment of diaper dermatitis.

**Please see full Prescribing Information for Desonate at www.Desonate.com.**

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit **www.FDA.gov/medwatch** or call **1-888-INFO-FDA**.

See Brief Summary of patient prescribing information on reverse side.

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**Initial U.S. Approval: 1972**

## BRIEF SUMMARY

## CONSULT PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION

### 1 INDICATIONS AND USAGE

Desonate is indicated for the treatment of mild to moderate atopic dermatitis in patients 3 months of age and older.

Patients should be instructed to use Desonate for the minimum amount of time as necessary to achieve the desired results because of the potential for Desonate to suppress the hypothalamic-pituitary-adrenal (HPA) axis *[see Warnings and Precautions (5.1)]*. Treatment should not exceed 4 consecutive weeks *[see Dosage and Administration (2)].*

### 4 CONTRAINDICATIONS

Desonate is contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation.

### 5 WARNINGS AND PRECAUTIONS

#### 5.1 Effects on Endocrine System

Systemic absorption of topical corticosteroids can produce reversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for clinical glucocorticosteroid insufficiency. This may occur during treatment or upon withdrawal of the topical corticosteroid.

The effect of Desonate on HPA axis function was investigated in pediatric subjects, 6 months to 6 years old, with atopic dermatitis covering at least 35% of their body, who were treated with Desonate twice daily for 4 weeks. One of 37 subjects (3%) displayed adrenal suppression after 4 weeks of use, based on the cosyntropin stimulation test. As follow-up evaluation of the subject's adrenal axis was not performed, it is unknown whether the suppression was reversible *[see Use In Specific Populations (8.4) and Clinical Pharmacology (12.2)]*.

Pediatric patients may be more susceptible than adults to systemic toxicity from equivalent doses of Desonate due to their larger skin surface-to-body mass ratios *[see Use In Specific Populations (8.4)]*.

Because of the potential for systemic absorption, use of topical corticosteroids may require that patients be periodically evaluated for HPA axis suppression. Factors that predispose a patient using a topical corticosteroid to HPA axis suppression include the use of more potent steroids, use over large surface areas, use over prolonged periods, use under occlusion, use on an altered skin barrier, and use in patients with liver failure.

An ACTH stimulation test may be helpful in evaluating patients for HPA axis suppression. If HPA axis suppression is documented, an attempt should be made to gradually withdraw the drug, to reduce the frequency of application, or to substitute a less potent steroid. Manifestations of adrenal insufficiency may require supplemental systemic corticosteroids. Recovery of HPA axis function is generally prompt and complete upon discontinuation of topical corticosteroids.

Cushing's syndrome, hyperglycemia, and unmasking of latent diabetes mellitus can also result from systemic absorption of topical corticosteroids.

Use of more than one corticosteroid-containing product at the same time may increase the total systemic corticosteroid exposure.

#### 5.2 Local Adverse Reactions with Topical Corticosteroids

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

#### 5.3 Concomitant Skin Infections

If concomitant skin infections are present or develop during treatment, an appropriate antifungal or antibacterial agent should be used. If a favorable response does not occur promptly, use of Desonate should be discontinued until the infection is adequately controlled.

#### 5.4 Skin Irritation

If irritation develops, Desonate should be discontinued and appropriate therapy instituted. Allergic contact dermatitis with corticosteroids is usually diagnosed by observing failure to heal rather than noting a clinical exacerbation as with most topical products not containing corticosteroids. Such an observation should be corroborated with appropriate diagnostic patch testing.

### 6 ADVERSE REACTIONS

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 controlled clinical studies of 425 Desonate-treated subjects and 157 Vehicle-treated subjects, adverse events occurred at the application site in 3% of subjects treated with Desonate and the incidence rate was not higher compared with vehicle-treated subjects. The most common local adverse events in Desonate treated subjects were application site burning in 1% (4/425) and rash in 1% (3/425) followed by application site pruritus in <1% (2/425).

Adverse events that resulted in premature discontinuation of study drug in Desonate treated subjects were telangiectasia and worsening of atopic dermatitis in one subject each. Additional adverse events observed during clinical trials for patients treated with Desonate included headache in 2% (8/425) compared with 1% (2/157) in those treated with vehicle.

The following additional local adverse reactions have been reported infrequently with topical corticosteroids. They may occur more frequently with the use of occlusive dressings, especially with higher potency corticosteroids. These reactions are listed in an approximate decreasing order of occurrence: folliculitis, acneiform eruptions, hypopigmentation, perioral dermatitis, secondary infection, skin atrophy, striae, and miliaria.



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INSPIRATION

# Emme: Loving the skin you are in

**Question:** We've all made mistakes in our youth—can we escape our "skin sins"?
**Answer:** As Emme shows us, there are steps we can take to improve our complexions.

Supermodel Emme helps people feel better about their body image through talk shows, books, lectures and the internet, including her new site—Emmenation.com.

"I created Emmenation.com to advise women about facing life challenges and how to feel good about themselves," says the 47-year-old mother of a daughter, Toby.

Emme knows challenges—not only from fighting stereotypes to succeed as a plus-sized model, but also from battling Stage II Hodgkin's disease in 2007 (she is now cancer free). Through it all, she's learned to overcome past mistakes in order to move forward.

That's been especially the case with her skin. Like many women her age, Emme committed sun sins in her youth including using a reflector to boost her tan.

"I grew up in Saudi Arabia. I'm embarrassed to admit it, but we used baby oil and iodine when we went to the beach," she recalls. "When we were younger, we didn't make the connection to sun and wrinkles later in life," adds Emme.

## Outer beauty reflects inner health

Although she was relatively compliant in washing her face, like many women she also admitted to occasionally skipping makeup removal before going to bed. A glowing complexion is symbiotic with modeling and Emme began to worry if all of the sun damage from her youth could catch up with her career.

She became further obsessed with her health and appearance after her bout with cancer. She started seeking natural and organic products and eliminated chemicals and dyes. She linked what she ingested and the impact that had on her health and skin, vowing to get healthier by doing everything from drinking more water to researching how she could slow down the aging process.

That directed her to the nutrient lutein as a way to protect, restore and hydrate her skin. Emme has partnered with FloraGLO brand lutein, an ingredient in many vitamins, as well as functional foods and beverages. "I start my day by taking a vitamin with FloraGLO Lutein to make sure I keep my skin looking its best," Emme says.

"Most Americans are concerned with premature aging. Our desire for healthy, younger-looking skin is greater than ever because our outer appearance is a reflection of our inner health and we all want to feel good and look young," she said. "And we all want to feel good and look as young as we can."

**Emme**
Plus-size model

**To keep her skin healthy and looking youthful,** Emme takes a vitamin with FloraGLO Lutein as part of her daily beauty routine. A natural antioxidant, lutein protects, restores and hydrates skin. FloraGLO is one of her partners in EmmeNation. See www.floraglolutein.com for more information. *Emme is a paid FloraGLO spokesperson and currently takes and eye vitamin with FloraGLO.*

**FAYE BROOKMAN**
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NEWS

TIP 3 MOISTURIZE DAILY

QUESTION & ANSWER

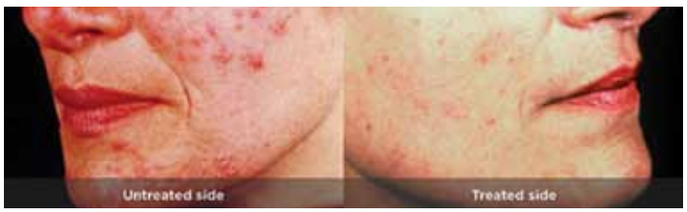
**James Q. Del Rosso, DO, FAOCD**
Clinical Professor of Dermatology, Touro University College of Osteopathic Medicine

**What causes rosacea?**
The course of rosacea over time varies from person to person, with many people noticing periodic flares of both the visible signs and symptoms of the disorder. Common environmental factors that do not cause rosacea itself, but tend to trigger a rosacea flare in many people are exposure to higher temperatures, such as on a hot day outdoors or after exercise or sauna use, and eating foods or drinking liquids that tend to dilate blood vessels in the skin, such as hot liquids (eg hot coffee or tea) or alcohol, especially red wine.

# The rosy glow of rosacea

**Question:** What did W. C. Fields, Princess Di, and Rembrandt have in common?
**Answer:** They all suffered from rosacea.

Fields' trademark bulbous, red nose and Diana's charming blush were both hallmarks of a frustrating and often embarrassing condition known as rosacea (pronounced rose-ay-shuh). Rosacea is an increasingly common skin disorder—as many as 14 million Americans suffer from the condition—that appears as rosy red patches primarily on the cheeks, nose, chin, or forehead. It typically develops when people are in their 30s, 40s or 50s. It often comes and goes, and sometimes goes into remission. However, when severe, it can result in visible blood vessels, a noticeable thickening of the skin, and a bumpy swollen nose.




## Not life-threatening

Certain triggers tend to set off a bout of rosacea. Exposure to sun or wind, emotional stress, heavy exercise, alcohol, and hot, humid weather are all common triggers. Even though rosacea is not life-threatening, the fact that it changes your appearance—and not always with the delicacy of Princess Diana—can make it a psychologically challenging condition. Though alcohol is a trigger for many people, rosacea is not an indication of alcoholism. However, the association with alcohol, perpetuated by Fields, can make the problem even more embarrassing.

## Managing the glow

Rosacea is a poorly understood condition and there is no cure. However, it can often be managed with careful choices. The National Rosacea Society advise a few basic measures to keep outbreaks to a minimum:

- Use sunscreen and wear a broad-brimmed hat when outdoors.
- Stay in a cool, air-conditioned environment on hot, humid days.
- Use a moisturizer daily, especially in cold weather.
- Avoid very hot beverages and very spicy food.
- Exercise frequently for short periods rather than for long stretches at a time.

If these measures are not enough, your doctor can prescribe medications that will help control the outbreaks.

Because rosacea is not well-known, people often make incorrect assumptions when they notice an acquaintance or a colleague with an outbreak. It can be very helpful to take the time to explain to them that your appearance is due to a skin condition. It is not contagious, is not caused by poor hygiene or excessive drinking, and will not affect your ability to work. A little candor can do a lot to ease the psychological distress of rosacea.

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Finacea®
(azelaic acid) Gel, 15%

**For Dermatologic Use Only–Not for Ophthalmic, Oral, or Intravaginal Use**

**Rx only**

**BRIEF SUMMARY**
**CONSULT PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION**

## INDICATIONS AND USAGE

FINACEA Gel, 15%, is indicated for topical treatment of inflammatory papules and pustules of mild to moderate rosacea. Although some reduction of erythema which was present in patients with papules and pustules of rosacea occurred in clinical studies, efficacy for treatment of erythema in rosacea in the absence of papules and pustules has not been evaluated. Patients should be instructed to avoid spicy foods, thermally hot foods and drinks, alcoholic beverages and to use only very mild soaps or soapless cleansing lotion for facial cleansing.

## CONTRAINDICATIONS

FINACEA Gel, 15%, is contraindicated in individuals with a history of hypersensitivity to propylene glycol or any other component of the formulation.

## WARNINGS

FINACEA Gel, 15%, is for dermatologic use only, and not for ophthalmic, oral or intravaginal use.

There have been isolated reports of hypopigmentation after use of azelaic acid. Since azelaic acid has not been well studied in patients with dark complexion, these patients should be monitored for early signs of hypopigmentation.

## PRECAUTIONS

***General:*** Contact with the eyes should be avoided. If sensitivity or severe irritation develops with the use of FINACEA Gel, 15%, treatment should be discontinued and appropriate therapy instituted.

In a transgenic mouse study, chronic use of FINACEA Gel led to an increased number of animals with papillomas at the treatment site (**see PRECAUTIONS: Carcinogenesis, Mutagenesis, and Impairment of Fertility**). The clinical relevance of the findings in animal studies to humans is not clear.

***Information for Patients:*** Patients using FINACEA Gel, 15%, should receive the following information and instructions:

- FINACEA Gel, 15%, is to be used only as directed by the physician.
- FINACEA Gel, 15%, is for external use only. It is not to be used orally, intravaginally, or for the eyes.
- Cleanse affected area(s) with a very mild soap or a soapless cleansing lotion and pat dry with a soft towel before applying FINACEA Gel, 15%. Avoid alcoholic cleansers, tinctures and astringents, abrasives and peeling agents.
- Avoid contact of FINACEA Gel, 15%, with the mouth, eyes and other mucous membranes. If it does come in contact with the eyes, wash the eyes with large amounts of water and consult a physician if eye irritation persists.
- The hands should be washed following application of FINACEA Gel, 15%.
- Cosmetics may be applied after FINACEA Gel, 15%, has dried.
- Skin irritation (e.g., pruritus, burning, or stinging) may occur during use of FINACEA Gel, 15%, usually during the first few weeks of treatment. If irritation is excessive or persists, use of FINACEA Gel, 15%, should be discontinued, and patients should consult their physician (See **ADVERSE REACTIONS**).
- Avoid any foods and beverages that might provoke erythema, flushing, and blushing (including spicy food, alcoholic beverages, and thermally hot drinks, including hot coffee and tea).
- Patients should report abnormal changes in skin color to their physician.
- Avoid the use of occlusive dressings or wrappings.

***Drug Interactions:*** There have been no formal studies of the interaction of FINACEA Gel, 15%, with other drugs.

***Carcinogenesis, Mutagenesis, Impairment of Fertility:***

Systemic long-term animal studies have not been performed to evaluate the carcinogenic potential of azelaic acid. In a 26-week dermal carcinogenicity study using transgenic (Tg.AC) mice, FINACEA Gel, 15%, and the gel vehicle, when applied once or twice daily, did not increase the number of female Tg.AC animals with papillomas at the treatment site. No statistically significant increase in the number of animals with papillomas at the treatment site was observed in male Tg.AC animals after once daily application. After twice daily application, FINACEA Gel, 15%, and the gel vehicle induced a statistically significant increase in the number of male animals with papillomas at the treatment site when compared to untreated males. This suggests that the positive effect may be associated with the vehicle application. The clinical relevance of the findings in animals to humans is not clear.

Azelaic acid was not mutagenic or clastogenic in a battery of *in vitro* (Ames assay, HGPRT in V79 cells {Chinese hamster lung cells}, and chromosomal aberration assay in human lymphocytes) and *in vivo* (dominant lethal assay in mice and mouse micronucleus assay) genotoxicity tests.

Oral administration of azelaic acid at dose levels up to 2500 mg/kg/day (162 times the maximum recommended human dose based on body surface area) did not affect fertility or reproductive performance in male or female rats.

***Pregnancy:*** *Teratogenic Effects: Pregnancy Category B*

There are no adequate and well-controlled studies of topically administered azelaic acid in pregnant women. The experience with FINACEA Gel, 15%, when used by pregnant women is too limited to permit assessment of the safety of its use during pregnancy.

Dermal embryofetal developmental toxicology studies have not been performed with azelaic acid, 15%, gel. Oral embryofetal developmental studies were conducted with azelaic acid in rats, rabbits, and cynomolgus monkeys. Azelaic acid was administered during the period of organogenesis in all three animal species. Embryotoxicity was observed in rats, rabbits, and monkeys at oral doses of azelaic acid that generated some maternal toxicity. Embryotoxicity was observed in rats given 2500 mg/kg/day (162 times the maximum recommended human dose based on body surface area), rabbits given 150 or 500 mg/kg/day (19 or 65 times the maximum recommended human dose based on body surface area) and cynomolgus monkeys given 500 mg/kg/day (65 times the maximum recommended human dose based on body surface area) azelaic acid. No teratogenic effects were observed in the oral embryofetal developmental studies conducted in rats, rabbits and cynomolgus monkeys.

An oral peri- and post-natal developmental study was conducted in rats. Azelaic acid was administered from gestational day 15 through day 21 postpartum up to a dose level of 2500 mg/kg/day. Embryotoxicity was observed in rats at an oral dose that generated some maternal toxicity (2500 mg/kg/day; 162 times the maximum recommended human dose based on body surface area). In addition, slight disturbances in the post-natal development of fetuses was noted in rats at oral doses that generated some maternal toxicity (500 and 2500 mg/kg/day; 32 and 162 times the maximum recommended human dose based on body surface area). No effects on sexual maturation of the fetuses were noted in this study.

Because animal reproduction studies are not always predictive of human response, this drug should be used only if clearly needed during pregnancy.

***Nursing Mothers:*** Equilibrium dialysis was used to assess human milk partitioning *in vitro*. At an azelaic acid concentration of 25 µg/mL, the milk/plasma distribution coefficient was 0.7 and the milk/buffer distribution was 1.0, indicating that passage of drug into maternal milk may occur. Since less than 4% of a topically applied dose of azelaic acid cream, 20%, is systemically absorbed, the uptake of azelaic acid into maternal milk is not expected to cause a significant change from baseline azelaic acid levels in the milk. However, caution should be exercised when FINACEA Gel, 15%, is administered to a nursing mother.

***Pediatric Use:*** Safety and effectiveness of FINACEA Gel, 15%, in pediatric patients have not been established.

***Geriatric:*** Clinical studies of FINACEA Gel, 15%, did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

## ADVERSE REACTIONS

Overall, treatment related adverse events, including burning, stinging/ tingling, dryness/tightness/ scaling, itching, and erythema/irritation/ redness, were 19.4% (24/124) for FINACEA Gel, 15%, and 7.1% (9/127) for the active comparator gel at 15 weeks.

In two vehicle controlled, and one active controlled U.S. clinical studies, treatment safety was monitored in 788 patients who used twice daily FINACEA Gel, 15%, for 12 weeks (N=333) or for 15 weeks (N=124), or the gel vehicle (N=331) for 12 weeks.

**Table 3. Cutaneous Adverse Events Occurring in ≥1% of Subjects in the Rosacea Trials by Treatment Group and Maximum Intensity***

| | FINACEA Gel, 15% N=457 (100%) | | | Vehicle N=331 (100%) | | |
|---|---|---|---|---|---|---|
| | Mild n=99 (22%) | Moderate n=61 (13%) | Severe n=27 (6%) | Mild n=46 (14%) | Moderate n=30 (9%) | Severe n=5 (2%) |
| Burning/ stinging/ tingling | 71 (16%) | 42 (9%) | 17 (4%) | 8 (2%) | 6 (2%) | 2 (1%) |
| Pruritus | 29 (6%) | 18 (4%) | 5 (1%) | 9 (3%) | 6 (2%) | 0 (0%) |
| Scaling/dry skin/xerosis | 21 (5%) | 10 (2%) | 5 (1%) | 31 (9%) | 14 (4%) | 1 (<1%) |
| Erythema/ irritation | 6 (1%) | 7 (2%) | 2 (<1%) | 8 (2%) | 4 (1%) | 2 (1%) |
| Contact dermatitis | 2 (<1%) | 3 (1%) | 0 (0%) | 1 (<1%) | 0 (0%) | 0 (0%) |
| Edema | 3 (1%) | 2 (<1%) | 0 (0%) | 3 (1%) | 0 (0%) | 0 (0%) |
| Acne | 3 (1%) | 1 (<1%) | 0 (0%) | 1 (<1%) | 0 (0%) | 0 (0%) |

*Subjects may have >1 cutaneous adverse event; thus, the sum of the frequencies of preferred terms may exceed the number of subjects with at least 1 cutaneous adverse event.

FINACEA Gel, 15%, and its vehicle caused irritant reactions at the application site in human dermal safety studies. FINACEA Gel, 15%, caused significantly more irritation than its vehicle in a cumulative irritation study. Some improvement in irritation was demonstrated over the course of the clinical studies, but this improvement might be attributed to subject dropouts. No phototoxicity or photoallergenicity were reported in human dermal safety studies.

In patients using azelaic acid formulations, the following additional adverse experiences have been reported rarely: worsening of asthma, vitiligo depigmentation, small depigmented spots, hypertrichosis, reddening (signs of keratosis pilaris), and exacerbation of recurrent herpes labialis.

Post-marketing safety-Skin: facial burning and irritation; Eyes: iridocyclitis on accidental exposure with FINACEA Gel, 15%, to the eye (see **PRECAUTIONS**).

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www.myfinacea.com



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# Take control of managing your mild to moderate rosacea with Finacea® (azelaic acid) Gel, 15%

**FINACEA is unique – it is the first and only FDA-approved gel for treating the bumps, pimples and associated redness of mild to moderate rosacea.**

**Ask your healthcare professional if FINACEA is right for you!**

**FREE**

## Available in March – The Rosacea App!

Free for download on iPhone, Blackberry and Android.

Visit **MyFinacea.com** for more information.


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**IMPORTANT SAFETY INFORMATION**

FINACEA is for dermatologic use only, and not for ophthalmic, oral, or intravaginal use. FINACEA is contraindicated in individuals with a history of hypersensitivity to propylene glycol or any other component of the formulation. In clinical trials, sensations of burning/stinging/tingling occurred in 29% of patients, and itching in 11%, regardless of the relationship to therapy. Post-marketing safety - Skin: facial burning and irritation; Eyes: iridocyclitis on accidental exposure to the eye. There have been isolated reports of hypopigmentation after use of azelaic acid. Since azelaic acid has not been well studied in patients with a dark complexion, these patients should be monitored for early signs of hypopigmentation.

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**Please see full Prescribing Information for FINACEA at www.MyFinacea.com.**

See Brief Summary of patient prescribing information on reverse page.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit **www.FDA.gov/medwatch** or call **1-888-INFO-FDA**

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