Finacea® Foam is a topical prescription medicine used to treat the inflammatory papules (raised spots) and pustules (pimple-like bumps) of mild to moderate rosacea.



Discover Finacea® Foam

Finacea® (azelaic acid)
Foam, 15%



Please see Important Safety Information throughout and on pages 18-19 and <u>accompanying</u> full Prescribing Information.

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#### What is Finacea® Foam used for?

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Not actual size.

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# Understanding rosacea

## What is rosacea?

Rosacea (roh-ZAY-sha) is a chronic condition that mostly affects the skin on your face.

Rosacea has many symptoms, primarily:

- Raised spots and pimple-like bumps, sometimes with pus inside
- Tiny blood vessels that can be seen through the skin
- Forehead, nose, cheeks, and chin that are often red (flushing)

Without treatment, the symptoms of rosacea may get worse.



# Who gets rosacea?

Rosacea is common, especially in men and women with fair or light-colored skin. It often appears when you're in your 30s or older. In an early stage, you might mistake rosacea for a sunburn and then ignore it. Rosacea doesn't go away, and it can get worse without treatment.

It's important to treat and manage rosacea as early as possible, before bumps and pimples get worse. Unfortunately, there's no cure for rosacea, but many people have been able to manage it by avoiding triggers and using a prescription medication.

# Common triggers

The following things may cause ("trigger") rosacea flare-ups\*:

- Sun—time spent in the sun is a top trigger for flare-ups. Use daily sun protection! Ask your healthcare professional about a sunscreen that may be right for you
- Strong wind; very cold or warm and humid conditions
- Spicy food and drinks, and those that are hot in temperature (for example, hot coffee and tea)
- Alcoholic drinks
- Certain foods such as chocolate, cheese, sour cream, yogurt, vinegar, citrus fruits, tomatoes, and bananas
- Stress and anxiety
- Skin care products with alcohol, witch hazel, acetone, or fragrance

Use the "Rosacea Diary" from the National Rosacea Society (NRS), a free booklet to help you find and avoid your personal rosacea triggers.

\*According to patient histories and a survey from the National Rosacea Society.

Visit the NRS website at http://www.rosacea.org/patients/materials/diary/index.php to order a copy.

# Ready to take the next step?

You may have tried many different medicines. Or, you may not be sure what to do next. Either way, like many people coping with the inflammatory papules (raised spots) and pustules (pimple-like bumps) of mild to moderate rosacea, you're taking action. Although rosacea can't be cured, it can be managed.

# Smooth it on—treating with Finacea® Foam



Not actual size.

## What is Finacea® Foam used for?

Finacea® Foam is a topical prescription medicine used to treat the inflammatory papules (raised spots) and pustules (pimple-like bumps) of mild to moderate rosacea.

# What should I tell my healthcare professional about CHANGES IN MY SKIN color during use of Finacea® Foam?

Report abnormal changes in skin color to your healthcare professional. There have been isolated reports of loss of skin color (hypopigmentation) after the use of azelaic acid (the active ingredient in Finacea® Foam). If you have a dark complexion, your healthcare professional will monitor you for early signs of loss of skin color.

Please see additional Important Safety Information throughout and on pages 18-19 and <u>accompanying</u> full Prescribing Information.

# Avoiding triggers

# Use Finacea® Foam exactly the way your healthcare professional tells you to!

Even if you are using your medicine the right way, certain things (known as triggers) can make your symptoms worse or cause flare-ups.

Triggers can be found everywhere—and they vary for each person. Here are some good ideas:

- Learn what your triggers are and how to avoid them
- Keep track of when you use Finacea® Foam
- Share this information with your healthcare professional at your next checkup so that he or she will know how Finacea® Foam is working for you

## What should I AVOID when using Finacea® Foam?

- Avoid contact with the eyes, mouth and other mucous membranes.
   Azelaic acid has been reported to cause irritation of the eyes. If Finacea® Foam does come in contact with the eyes, wash the eyes with large amounts of water and consult your healthcare professional if eye irritation persists.
- Avoid fire, flame, and smoking during and immediately following application. Do not puncture and/or incinerate the containers. Do not expose containers to heat and/or store at temperatures above 120°F (49°C). The propellant in Finacea® Foam is flammable.
- Avoid the use of tight dressings or wrappings where you apply Finacea® Foam.
- Avoid use of alcoholic cleansers, tinctures and astringents, abrasives and peeling agents.

Finacea (azelaic acid)

# About Finacea® Foam

The first prescription foam approved for rosacea by the US Food and Drug Administration (FDA)

Finacea® Foam is proven to treat the inflammatory papules (raised spots) and pustules (pimple-like bumps) of mild to moderate rosacea.

- Finacea® Foam is a water-based (hydrophilic) foam that is light and airy
  - Not alcohol-based
  - Fragrance free
- Apply Finacea® Foam twice daily (morning and evening) to the entire facial area (cheeks, chin, forehead, and nose). For a single application, dispense the smallest amount of foam necessary to adequately cover the affected area(s) with a thin layer



- Shake well before use
- Cosmetics may be applied after the application of Finacea® Foam has dried
- Avoid the use of occlusive dressings or wrappings
- Finacea® Foam should be used continuously over 12 weeks
- Your healthcare professional will reassess your treatment if no improvement is observed upon completing 12 weeks of therapy
- Not for oral, ophthalmic or intravaginal use

Please see additional Important Safety Information throughout and on pages 18-19 and accompanying full Prescribing Information.

# What SAFETY FACTS should I follow when applying Finacea® Foam?

- Finacea® Foam is for topical use only.
- Do not use in the mouth, eye, or vagina.

# What are common side effects of Finacea® Foam?

In clinical studies, the most common side effects (in the places where it was applied) were:

- Pain (described as burning, stinging, "pins and needles" sensation, and/or tenderness) (6.2% of people)
- Itching (2.5% of people)
- Dryness (0.7% of people)
- Redness (0.7% of people)

# Tip!

Before using Finacea® Foam:

• Cleanse your face with mild soap

After using Finacea® Foam:

Wash your hands

Finacea® (azelaic acid)
Foam, 15%

# How could Finacea® Foam help me?

# Finacea® Foam may help you reduce the raised spots and pimple-like bumps of your mild to moderate rosacea

Here's what happened in the 2 clinical trials that each lasted 12 weeks:

- Finacea® Foam was superior (when compared to the same foam without drug) in reducing the number of raised spots and pimple-like bumps
- By looking at the skin of people who used Finacea® Foam, researchers found that they had better results than those who used the same foam without drug

# What are the MOST COMMON SIDE EFFECTS of Finacea® Foam?

Local site:

- pain (described as burning, stinging, "pins and needles," and/or tenderness)
- itching
- dryness
- redness

Please see additional Important Safety Information throughout and on pages 18-19 and accompanying full Prescribing Information.

## What is an IGA scale?

- IGA (Investigator's Global Assessment) scale is a scale of disease severity that is used in clinical studies to determine whether a person has achieved success over time
- People who were considered to have "success" ranged from "Clear" to "Minimal" AND had at least a 2-step improvement. For example, they went from "Moderate" to "Minimal" on the IGA scale at the end of the trials











Success is defined as a score of "Clear" or "Minimal" with at least a 2-step reduction from baseline on a 5-point IGA. Graphic representation is for illustrative purposes only.

#### Finacea® Foam was tested in 2 vehicle-controlled trials



#### **Vehicle-controlled** means:

Some people in the studies received a **foam (vehicle) without drug**, while **others received Finacea® Foam**. This is a common way for researchers to study the effectiveness of medicines.

Finacea® (azelaic acid)
Foam, 15%

# Finacea® Foam was shown to reduce the number of raised spots and pimple-like bumps

Finacea® Foam is proven to treat the raised spots (also called *inflammatory papules*) and pimple-like bumps (also called *pustules*) of mild to moderate rosacea

 At the end of 12 weeks, researchers evaluated the changes they saw in the people in the trials

After 12 weeks of treatment with Finacea® Foam

#### Before



#### **After**



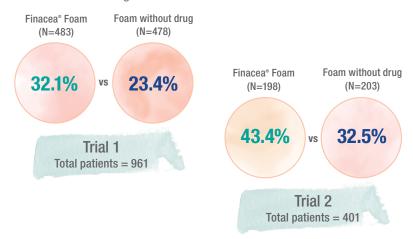
Actual photo of a Finacea® Foam phase 3 clinical-trial subject. All patients may not exhibit the same results.

Please see additional Important Safety Information throughout and on pages 18-19 and accompanying full Prescribing Information.

## The look of success

In both 12-week trials with 1,362 people...

Researchers observed superior IGA success rates with Finacea® Foam vs the foam without drug at the end of 12 weeks of treatment



# What should I tell my healthcare professional about CHANGES IN MY SKIN color during use of Finacea® Foam?

Report abnormal changes in skin color to your healthcare professional. There have been isolated reports of loss of skin color (hypopigmentation) after the use of azelaic acid (the active ingredient in Finacea® Foam).

If you have a dark complexion, your healthcare professional will monitor you for early signs of loss of skin color.

Finacea® (azelaic acid)
Foam, 15%

# Using Finacea® Foam: Your step-by-step guide

Follow the steps below to apply Finacea® Foam twice daily (morning and evening) or as your healthcare professional has prescribed. Finacea® Foam is for external use only.



- Clean your face with very mild soap or soapless cleansing lotion
- Avoid the use of alcoholic cleansers, tinctures and astringents, abrasives and peeling agents



2

Pat your skin dry with a soft towel





To help manage rosacea, avoid any triggers that may provoke erythema, flushing, and blushing. These triggers can include spicy and thermally hot food and drinks such as hot coffee, tea, or alcoholic beverages.

Please see additional Important Safety Information throughout and on pages 18-19 and <u>accompanying</u> full Prescribing Information.

# What should I AVOID when using Finacea® Foam?

- Avoid contact with the eyes, mouth and other mucous membranes.
   Azelaic acid has been reported to cause irritation of the eyes. If
  Finacea® Foam does come in contact with the eyes, wash the eyes
  with large amounts of water and consult your healthcare professional
  if eye irritation persists.
- Avoid fire, flame, and smoking during and immediately following application. Do not puncture and/or incinerate the containers. Do not expose containers to heat and/or store at temperatures above 120°F (49°C). The propellant in Finacea® Foam is flammable.
- Avoid the use of tight dressings or wrappings where you apply Finacea® Foam.
- Avoid use of alcoholic cleansers, tinctures and astringents, abrasives and peeling agents.

3.

 Shake Finacea® Foam well before using it



(Please turn the page for steps 4-6)

# What SAFETY FACTS should I follow when applying Finacea® Foam?

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- Do not use in the mouth, eye or vagina.

Finacea® (azelaic acid)
Foam, 15%

#### (Steps continued from previous page)

- 4.
- Hold the Finacea® Foam can upright
- Push the button to dispense the smallest amount of foam needed (just a dollop!) to cover the affected area(s) with a thin layer



5.

 Apply Finacea® Foam twice daily (morning and evening) to the entire facial area (cheeks, chin, forehead, and nose) or as directed by your healthcare professional



- Finacea® Foam should be used continuously over 12 weeks
- Your healthcare professional will reassess your treatment if no improvement is observed upon completing 12 weeks of therapy



- Wash your hands right after you use Finacea® Foam
- You can put on makeup and other cosmetics after Finacea® Foam dries on your skin. Consult your healthcare professional about cosmetics that are right for your skin.



 If allergic reactions occur, discontinue use and consult your physician



Discard product 8 weeks after opening.

Please see additional Important Safety Information throughout and on pages 18-19 and <u>accompanying</u> full Prescribing Information.

The can of Finacea® Foam is made of aluminum and you may be able to recycle it according to the guidelines of your state. Or, you can ask your local pharmacist how to dispose of the can.



Avoid fire, flame, and smoking during and immediately following application. The propellant in Finacea® Foam is flammable.

# What are the MOST COMMON SIDE EFFECTS of Finacea® Foam?

#### Local site:

- pain (described as burning, stinging, "pins and needles," and/or tenderness)
- itching
- dryness
- redness



Finacea® (azelaic acid)
Foam, 15%

# **INDICATION**

## What is Finacea® Foam used for?

Finacea® Foam is a topical prescription medicine used to treat the inflammatory papules (raised spots) and pustules (pimple-like bumps) of mild to moderate rosacea.

# IMPORTANT SAFETY INFORMATION

# What should I tell my healthcare professional about CHANGES IN MY SKIN color during use of Finacea® Foam?

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Local site:

- pain (described as burning, stinging, "pins and needles," and/or tenderness)
- itching
- dryness
- redness

You are encouraged to report side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088 (1-800-322-1088).

You may also report side effects to LEO Pharma Inc. at 1-877-494-4536, option 1, or email to usdrugsafety@leo-pharma.com

Please see <u>accompanying</u> full Prescribing Information.

Finacea® (azelaic acid)
Foam, 15%

# Inside: See before-and-after photos

Getting started with

# Finacea® (azelaic acid) Foam, 15%

www.FinaceaFoam.com

Finacea® Foam is a topical prescription medicine used to treat the inflammatory papules (raised spots) and pustules (pimple-like bumps) of mild to moderate rosacea.

Brought to you by LEO, the maker of Finacea® Foam.

Please see Important Safety Information throughout and on pages 18-19 and <u>accompanying</u> full Prescribing Information.

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