

Please see the full **Important Safety Information by tapping** the ISI button at the top. Please see the full **Prescribing Information** by tapping the PI button at the top.

Indication and Usage

Finacea[®] (azelaic acid) Foam, 15% is indicated for the topical treatment of inflammatory papules and pustules of mild to moderate rosacea.

Important Safety Information

For topical use only. Finacea Foam is not for oral, ophthalmic or intravaginal use.

lotion and pat dry with a soft towel.

Before applying Finacea Foam, cleanse affected area(s) using only very mild soaps or soapless cleansing

HONT POES FORAM meet function?

For a single application, dispense the smallest amount of foam necessary to adequately cover the affected area with a thin layer.¹

*Results from both primary endpoints demonstrated superior efficacy of Finacea[®] Foam over foam vehicle in 12-week clinical trials.¹

The first FDA-approved prescription foam for the topical treatment of the inflammatory papules and pustules of mild to moderate rosacea¹

PROVEN EFFICACY in clinical trials

Significant reduction in the mean number of inflammatory lesions with Finacea[®] Foam versus foam vehicle* at Week 12¹⁻³

Results from the 2 clinical trials. Week 4 and Week 8 time points were exploratory.

Treatment differences cannot be regarded as statistically significant.

Finacea[®] Foam should be used continuously over 12 weeks. Reassess patients if no improvement is observed upon completion of therapy.¹

*Foam vehicle contained the same exact hydrophilic foam minus azelaic acid.¹ [†]End of trial. [‡]*P*-value is calculated from 2-sided t test.

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Important Safety Information (cont'd)

-4 -6 -8 -10 -12

Lesion

n Inflammatory Le: Count Reduction

Mea





TRIAL 1

Apply a thin layer of Finacea Foam twice daily (morning and evening) to the entire facial area (cheeks, chin, forehead, and nose). Wash hands immediately after application.

Avoid the use of occlusive dressings or wrappings at the application site. Avoid use of alcoholic cleansers, tinctures and astringents, abrasives and peeling agents.

Patients should be reassessed if no improvement is observed upon completing 12 weeks of therapy.

TRIAL 2

PRIMARY ENDPOINT RESULTS



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Patients should be reassessed if no improvement is observed upon completing 12 weeks of therapy.

• Subjects' ages ranged from 19 to 92 years (mean age 50.6 years); 95.7% of subjects participating in the trials were Caucasian and 73.4% were female

• Enrolled patients had papulopustular rosacea with a mean lesion count of

PATIENTS

TROVEN IMPROVEMENTS in IGA* success rates¹

Significant improvement in IGA success rates with Finacea® Foam versus foam vehicle at Week 12¹⁻³

Results from the 2 clinical trials. Week 4 and Week 8 time points were exploratory. Treatment differences cannot be regarded as statistically significant.

Treatment success is defined as a score of "Clear" or "Minimal" with at least a 2-step reduction, "Moderate" to "Minimal," from baseline on a 5-point IGA.

Finacea[®] Foam should be used continuously over 12 weeks. Reassess patients if no improvement is observed upon completion of therapy.¹

*Investigator's Global Assessment. **P*-value is calculated from the Pearson χ^2 test.

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Important Safety Information (cont'd)

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Apply a thin layer of Fina chin, forehead, and nose Avoid the use of occlusiv cleansers, tinctures and Patients should be reass





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Finacea® (azelaic acid) Foam, 15%

TRIAL 2

PRIMARY ENDPOINT RESULTS

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Success is defined as at least a 2-step reduction

Success is defined as a score of "Clear" or "Minimal" with at least a 2-step reduction, "Moderate" to "Minimal" from baseline, or "Mild" to "Clear" from baseline on a 5-point IGA.¹

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Adverse reactions with Finacea[®] Foam versus foam vehicle

Adverse Reaction

Application site pain*

Application site pruritus

Application site dryness

Application site erythen

*Application site pain is a term used to describe disagreeable skin sensations, including burning, stinging, paraesthesia, and tenderness.

*Investigator's Global Assessment. [†]P-value is calculated from the Pearson χ2 test.

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Important Safety Information (cont'd)

Apply a thin layer of Fina chin, forehead, and nose Avoid the use of occlusiv cleansers, tinctures and Patients should be reass

Adverse reactions occurring in ≥0.5% of subjects¹

	Finacea® Foam, 15% (N=681) n (%)	
	42 (6.2%)	
S	17 (2.5%)	
SS	5 (0.7%)	
ma	5 (0.7%)	



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Patients should be reassessed if no improvement is observed upon completing 12 weeks of therapy.

Foam Vehicle (N=681) n (%)

10 (1.5%)

2 (0.3%)

5 (0.7%)

6 (0.9%)

RESULTS of the clinical trials: Secondary endpoints



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Important Safety Information (cont'd) Warnings and Precautions

- for early signs of hypopigmentation.
- irritation persists.

• Hypopigmentation: There have been isolated reports of hypopigmentation after use of azelaic acid. Because azelaic acid has not been well studied in patients with dark complexion, monitor these patients

 Eye and Mucous Membrane Irritation: Azelaic acid has been reported to cause irritation of the eyes. Avoid contact with the eyes, mouth and other mucous membranes. If Finacea Foam does come in contact with the eyes, wash the eyes with large amounts of water and consult a healthcare professional if eye

Mean percent change (from **baseline**) in inflammatory lesion count observed with **Finacea[®] Foam versus foam** vehicle over 12 weeks⁴⁻⁶

Results from the 2 clinical studies. Week 4, Week 8, and Week 12 time points were exploratory.

Treatment differences observed cannot be regarded as statistically significant.

Finacea[®] Foam should be used continuously over 12 weeks. Reassess patients if no improvement is observed upon completion of therapy.¹

RESULTS of the clinical trials: Secondary endpoints



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Change in therapeutic response rate with Finacea[®] Foam versus foam vehicle over 12 weeks⁴⁻⁶

Results from the 2 clinical studies. Week 4, Week 8, and Week 12 time points were exploratory.

Treatment differences observed cannot be regarded as statistically significant.

Therapeutic response rate is defined as the percentage of patients achieving IGA scores of "Clear," "Minimal," or "Mild."

BEFORE and AFTER photos

FINACEA[®] FOAM TREATMENT SUCCESS

These photos show individual subjects who met the criteria for success (a score of "Clear" or "Minimal" with at least a 2-step reduction from baseline on a 5-point IGA).⁶



Lesion count: 26

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Important Safety Information (cont'd) Warnings and Precautions (cont'd)

Adverse Reactions

• Flammability: The propellant in Finacea Foam is flammable. Instruct the patient to 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).

• In clinical studies, the most frequently observed adverse reactions reported in $\geq 0.5\%$ of subjects treated with Finacea Foam included local site pain (6.2%), pruritus (2.5%), dryness (0.7%), and erythema (0.7%).

Actual photos of 2 patients from the Finacea[®] Foam arm of the clinical trials. Individual results may vary.

Lesion count: 1

BEFORE and AFTER photos

FOAM VEHICLE TREATMENT SUCCESS

These photos show individual subjects who met the criteria for success (a score of "Clear" or "Minimal" with at least a 2-step reduction from baseline on a 5-point IGA).⁶



Baseline IGA score: 4 Lesion count: 24

Patient #15-006

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Important Safety Information (cont'd) Warnings and Precautions (cont'd)

Adverse Reactions

Week 12 IGA score: 1 Lesion count: 4

Baseline IGA score: 4 Lesion count: 23

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• In clinical studies, the most frequently observed adverse reactions reported in $\geq 0.5\%$ of subjects treated with Finacea Foam included local site pain (6.2%), pruritus (2.5%), dryness (0.7%), and erythema (0.7%).

Actual photos of 2 patients from the foam vehicle arm of the clinical trials. Individual results may vary.

Patient #15-009

Week 12 IGA score: 1 Lesion count: 0





AZELAIC ACID¹ suspended in an oil-in-water emulsion vehicle



FRAGRANCE FREE¹

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Important Safety Information (cont'd) Use in Specific Populations

Pregnancy: Azelaic acid is minimally absorbed systemically following topical route of administration, and maternal use is not expected to result in fetal exposure to the drug.

Lactation: Azelaic acid is naturally present in human milk. When used as prescribed, azelaic acid is unlikely to be absorbed through the skin in clinically relevant amounts to cause a change in azelaic acid concentration in milk or milk production; therefore, breastfeeding is not expected to result in exposure of the infant to Finacea Foam.



WATER BASED¹ (not alcohol based)



CONTAINS 2 EMOLLIENTS¹

(cetostearyl alcohol and medium-chain triglycerides, diglycerides, monoglycerides) and a humectant (propylene glycol)





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Did you know?

Rosacea is often thought of as a "woman's condition"

In the United States, 14 million people have been diagnosed with rosacea; about one-fourth of them are men.^{7,8}

Men tend to have more severe rosacea symptoms

Men are more than twice as likely to experience an enlarged, red nose with excess tissue, thickening of the skin, and irregular surface nodules due to rosacea. One reason for this—men may delay medical treatment until rosacea becomes advanced.⁷

People of color may be underdiagnosed or misdiagnosed

This may be due in part to a misconception that rosacea is a disease of fair-skinned people. Also, difficulty detecting its characteristics in those with darker skin is thought to lead to underdiagnosis.⁹

Actor portrayal. For illustrative purposes only.



• Not for oral, ophthalmic, or intravaginal use¹

FINACED® (azelaic acid) Foam, 15%

What patients REPORTED about Finacea® Foam

Global assessment of treatment response with Finacea® Foam versus foam vehicle at Week 12^{6,10}



Patient-reported data are based on opinions from study subjects. Outcomes were exploratory and cannot be regarded as statistically significant.

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Important Safety Information (cont'd) Use in Specific Populations (cont'd)

Pediatric Use: The safety and efficacy of Finacea Foam have not been established in pediatric patients.

You are encouraged to report side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088 (1-800-332-1088).

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



How patients rated the COSMETIC ACCETTABILITY of Finacea® Foam



reported very good, good, or satisfactory

85%

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Assessment of cosmetic acceptability of Finacea® Foam versus foam vehicle at Week 12^{6,10}

reported very good, good, or satisfactory

reported very good, good, or satisfactory

Patient-reported data are based on opinions from study subjects. Outcomes were exploratory and cannot be regarded as statistically significant.

reported very good, good, or satisfactory

CONSIDER. Finacea[®] Foam for your appropriate patients



TWICE-DAILY DOSING

Instruct patients to apply Finacea[®] Foam twice daily (morning and evening) to the entire facial area (cheeks, chin, forehead, and nose).¹



PROVEN EFFICACY PROFILE

Finacea[®] Foam was proven effective in two 12-week clinical trials.¹

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lotion and pat dry with a soft towel.



HYDROPHILIC FOAM

The first prescription foam approved by the FDA for the treatment of mild to moderate rosacea.¹

Before applying Finacea Foam, cleanse affected area(s) using only very mild soaps or soapless cleansing







reduce out-of-pocket expension For more question TO ACTIVATE 1 or call 1-888-7 SEE REVERSE

Not an actual co-pay card.

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ACCESS to Finacea[®] Foam through LEO Pharma[®] CONNECT

Most eligible commercially insured patients may pay as little as



Tap here for full Terms and Conditions and Eligibility Requirements.

*Certain restrictions apply. This card may reduce out-of-pocket expenses. Patient must be 18 years of age or older to use this card. If patient is under 18, a legal guardian over 18 years of age may access this program on your behalf where permitted by, and consistent with, additional restrictions imposed by law (and subject to any additional age restrictions that relate to each product). Patients are not eligible if they are enrolled or they participate in any state or federally funded healthcare program (eg, Medicare, Medicaid, etc). For eligibility requirements and restrictions, visit leopharmaconnect.com or call 1-877-678-7494.

Before applying Finacea Foam, cleanse affected area(s) using only very mild soaps or soapless cleansing

per prescription at any pharmacy*

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immediately after application. Avoid the use of occlusive dressings or wrappings at the application site. Avoid use of alcoholic cleansers, tinctures and astringents, abrasives and peeling agents.

Patients should be reassessed if no improvement is observed upon completing 12 weeks of therapy.

Warnings and Precautions

- healthcare professional if eye irritation persists.

Adverse Reactions

(6.2%), pruritus (2.5%), dryness (0.7%), and erythema (0.7%).

Use in Specific Populations

Pregnancy: Azelaic acid is minimally absorbed systemically following topical route of administration, and maternal use is not expected to result in fetal exposure to the drug.

Lactation: Azelaic acid is naturally present in human milk. When used as prescribed, azelaic acid is unlikely to be absorbed through the skin in clinically relevant amounts to cause a change in azelaic acid concentration in milk or milk production; therefore, breastfeeding is not expected to result in exposure of the infant to Finacea Foam.

Pediatric Use: The safety and efficacy of Finacea Foam have not been established in pediatric patients.

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• Eye and Mucous Membrane Irritation: Azelaic acid has been reported to cause irritation of the eyes. Avoid contact with the eyes, mouth and other mucous membranes. If Finacea Foam does come in contact with the eyes, wash the eyes with large amounts of water and consult a

• Flammability: The propellant in Finacea Foam is flammable. Instruct the patient to 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).

• In clinical studies, the most frequently observed adverse reactions reported in $\geq 0.5\%$ of subjects treated with Finacea Foam included local site pain

You are encouraged to report side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call

References

1. Finacea[®] Foam [prescribing information]. LEO Pharma Inc.

2. Draelos ZD, Elewski BE, Harper JC, et al. A phase 3 randomized, double-blind, vehicle-controlled trial of azelaic acid foam 15% in the treatment of papulopustular rosacea. 2016 35th Anniversary Fall Clinical Dermatology Conference, Las Vegas, Nevada, October 20-23, 2016. **3.** Draelos ZD, Elewski B, Staedler G, et al. Azelaic acid foam 15% in the treatment of papulopustular rosacea. A randomized, double-blind, vehicle

controlled study. *Cutis*. 2013;92(1):306-317.

4. Solomon JA, Tyring S, Staedtler G, et al. Investigator-reported efficacy of azelaic acid foam 15% in patients with papulopustular rosacea: secondary efficacy endpoints from a randomized, controlled, double-blind, phase 3 trial. Cutis. 2016;98:187-194.

5. Solomon JA, Tyring S, Staedtler G, et al. Investigator-reported efficacy of azelaic acid foam 15% in patients with papulopustular rosacea: secondary efficacy endpoints from a randomized, controlled, double-blind, phase 3 trial. Paper presented at: Fall Clinical Dermatology Conference; October 20-23, 2016; Las Vegas, Nevada.

6. Data on File. LEO Pharma Inc.

7. Rosacea. Cleveland Clinic. Updated October 10, 2019. Accessed January 31, 2021. https://my.clevelandclinic.org/health/diseases/12174-rosacea-adult-acne

8. Men with rosacea face different symptoms. National Rosacea Society. Updated June 29, 2015. Accessed January 31, 2021. https://www.rosacea.org/blog/2015/june/men-with-rosacea-face-different-symptoms

9. Alexis AF, Callender VD, Baldwin HE, et al. Global epidemiology and clinical spectrum of rosacea, highlighting skin of color: review and clinical practice experience. J Am Acad Dermatol. 2019;80(6):1722-1729.

10. Tyring S, Soloman JA, Staedtler G, Lott JP, Nkulikiyinka R, Shakery K. Patientreported outcomes of azelaic acid foam 15% for patients with papulopustular rosacea: secondary efficacy results from a randomized, controlled, double-blind, phase 3 trial. Cutis. 2016;98(4):269-275.

