Package leaflet: Information for the user

Finacea® 15 % Gel

Azelaic acid

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. **What Finacea® is and what it is used for**
2. **What you need to know before you use Finacea®**
3. **How to use Finacea®**
4. **Possible side effects**
5. **How to store Finacea®**
6. **Contents of the pack and other information**

1. What Finacea® is and what it is used for

Finacea 15 % Gel (Finacea) contains the active substance azelaic acid and belongs to the group of anti-acne preparations for external use (on the skin). Finacea is for the relief of mild to moderate papulopustular acne of the face and the treatment of papulopustular rosacea. Papulopustular acne and rosacea are associated with inflamed papules and pustules.

2. What you need to know before you use Finacea®

Do not use Finacea
- if you are allergic to azelaic acid or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or pharmacist before using Finacea.

Finacea is for external use on the skin only.

Take care to avoid contact with the eyes, mouth and other mucous membranes (the thin skin around body openings).

In the event of an accidental contact, wash the eyes, mouth and/or affected mucous membranes with large amounts of water. You should consult a doctor or pharmacist if an eye irritation persists.

Please wash your hands after each application of Finacea.

It is advisable to avoid alcoholic cleansers, tinctures and astringents, abrasives and peeling agents when using Finacea for treatment of rosacea.

Rarely, it has been reported that in some patients with asthma who were treated with azelaic acid worsening of asthma symptoms had occurred.

Children and adolescents
Safety and efficacy in the treatment of acne have been studied in 12-18 years old adolescents (see section 3. How to use Finacea).

Finacea is not recommended for the treatment of acne in children below the age of 12 due to a lack of data on safety and efficacy.

Finacea is not recommended for the treatment of rosacea in children below the age of 18 due to a lack of data on safety and efficacy.

Other medicines and Finacea
It has not been studied whether Finacea affects or is affected by other medicines.

Do not apply other medicines or treatments to your face at the same time as Finacea.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregnancy and breast-feeding
There is limited experience from use of azelaic acid during pregnancy. If you are pregnant or breast-feeding, your doctor will decide whether you can use Finacea.

Infants must not come into contact with treated skin or breast.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines
Finacea has no influence on the ability to drive and use machines.

Finacea Gel contains benzoic acid, propylene glycol and polysorbate 80
Finacea Gel contains 1 mg benzoic acid in each g. Benzoic acid may cause local irritation.

Finacea Gel contains 120 mg propylene glycol in each g.

Finacea Gel contains 15 mg polysorbate 80 in each g. Polysorbates can cause allergic reactions.

3. How to use Finacea®

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Finacea is intended for external use on the skin only.

- **Before you apply Finacea, clean the skin thoroughly with water and dry.** You may use a mild skin-cleansing agent.
- Do not use air- and water-tight (occlusive) dressings or wrappings, and **wash your hands after applying the gel**.
- **Apply Finacea to the affected skin areas twice a day** (in the morning and in the evening) and rub it gently into the skin. Approximately 2.5 cm, which is equal to 0.5 g (1 inch) of gel, is sufficient for the entire face.

Finacea works more effectively if used continuously over the entire period of treatment.

In the event of an irritation of the skin (see section 4. Possible side effects), reduce the amount of gel per application or the frequency of use of Finacea to once a day until the irritation ceases. If necessary, you should interrupt the treatment temporarily for a few days.

Use in children and adolescents
Dose adjustment in children aged 12-18 years treated for acne is not necessary.

Duration of treatment
How long Finacea has to be used can vary from person to person and also depends on the severity of the skin disorder.

Your doctor will tell you how long you should use Finacea.

Acne: You can use Finacea over several months depending on the effect of the treatment. In general, you may notice a distinct improvement after 4 weeks. In case of no improvement after 1 month or if the acne becomes worse, you should discontinue Finacea and consult your doctor.

Rosacea: You can use Finacea over several months depending on the effect of the treatment. You may notice a distinct improvement after 4 weeks of the treatment. In case of no improvement after 2 months or if the rosacea becomes worse, you should discontinue Finacea and consult your doctor.

If you use more Finacea than you should
Even if you have accidentally used more Finacea than you should, a harmful effect (intoxication) is unlikely. Please continue as prescribed and ask your doctor if you are not sure.

If you forget to use Finacea
Do not use twice the amount to make up for a forgotten treatment. Continue as prescribed by your doctor.

If you stop using Finacea
If you stop using Finacea your skin disease can get worse. Please ask your doctor before you stop using Finacea. If you have any further questions on the use of Finacea, ask your doctor or pharmacist.

Mock-up Approval Stamp (MAS)

3. PROOF FROM DVRDK — Date 27/11/2025

New proof requested ☐ — Sign.: Date:

Graphic Design — **According to:** SOP_000647, SOP_000962, SOP_003993 and SOP_008676 — 1st Sign.: Date: ☐

Editorial Proof — **According to:** SOP_000647, SOP_000962 and SOP_008676 — Sign.: Date: ☐

Second Approver

Product name	☐
Dosage form	☐
Strength/Stripes	☐
Pack size	☐
Prompts	☐
Material No./Reg. No.	☐
Barcode	☐

Sign.: Date:

4. Possible side effects

Like all medicines, Finacea can cause side effects, although not everybody gets them.

You must get urgent medical help if you have any of the following symptoms. You may be having an allergic reaction. This is rare and may affect up to 1 in 1,000 people:

- **Angioedema (rapid swelling under the skin)**
- **Eye swelling**
- **Swelling face**
- **Dyspnoea (shortness of breath)**

Skin irritations (for example burning and itching) may occur.
In the majority of cases, the irritation symptoms are mild or moderate and their frequency decreases during the course of therapy.

The most frequently observed side effects included itching (pruritis), burning and pain at the application site.

The following side effects may occur during the treatment with Finacea Gel. They only concern the skin in the application area:

Acne:
Very common (may affect more than 1 in 10 people): Burning, pain, itching (pruritis) at the application site

Common (may affect up to 1 in 10 people): Rash, feeling of tingling or numbness (paraesthesia), dry skin at the application site

Uncommon (may affect up to 1 in 100 people): Skin reaction due to an external agent (contact dermatitis), abnormal redness of the skin (erythema); scaling, warmth, skin discolouration at the application site

Rare (may affect up to 1 in 1,000 people) [1]:
- Skin irritation
- Urticaria (hives)
- Worsening of asthma.

[1] These side effects have been reported in patients using azelaic acid since marketing approval.

Rosacea:
Very common (may affect more than 1 in 10 people): Burning, pain, itching (pruritus) at the application site

Common (may affect up to 1 in 10 people): Feeling of tingling or numbness (paraesthesia), dry skin, rash, swelling (oedema) at the application site

Uncommon (may affect up to 1 in 100 people): Acne, skin reaction due to an external agent (contact dermatitis), abnormal redness of the skin (erythema); nettle rash (urticaria), discomfort at the application site

Rare (may affect up to 1 in 1,000 people) [1]:
- Skin irritation
- Urticaria (hives)
- Worsening of asthma.

[1] These side effects have been reported in patients using azelaic acid since marketing approval.

Children and adolescents
Treatment of acne vulgaris in adolescents 12-18 years of age:

In clinical studies involving adolescents, the overall incidence of adverse events for Finacea was similar to that for the entire patient population.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Finacea®

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the carton and tube after "EXP". The expiry date refers to the last day of that month.

Finacea does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines no longer required. These measures will help protect the environment.

6. Contents of the pack and other information

What Finacea contains
- The active substance is azelaic acid (Each gram of Finacea contains 150 mg of azelaic acid).
- The other ingredients are: Benzoic acid (E210), carbomers, disodium edetate, lecithin, polysorbate 80, propylene glycol, purified water, sodium hydroxide and triglycerides medium chain.

What Finacea looks like and contents of the pack
Finacea is a white to yellowish-white opaque gel.
Finacea is available in pack sizes of 5, 30, 50 or 2 x 50 g of gel.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
LEO Laboratories Limited
Maidenhead, Berkshire SL6 3UD, UK

Manufactured by:
LEO Pharma Manufacturing Italy S.r.l.
Via E. Schering 21, 20054 Segrate (Milan), Italy

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