**Package leaflet: Information for the user**

**Skinoren® 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**


## 1. What Skinoren® Gel is and what it is used for

Skinoren Gel contains the active substance azelaic acid and belongs to the group of anti-acne preparation for external (cutaneous) use. Skinoren Gel 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 Skinoren® Gel

**Do not use Skinoren Gel**

- 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, pharmacist or nurse before using Skinoren Gel.

Skinoren Gel is for external (cutaneous) use only.

Take care to avoid contact with the eyes, mouth and other mucous membranes. 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 Skinoren Gel.
It is advisable to avoid alcoholic cleansers, tinctures and astringents, abrasives and peeling agents when using Skinoren Gel 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 Skinoren Gel"). Skinoren Gel 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.
Skinoren Gel 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 Skinoren Gel**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
It has not been studied whether Skinoren Gel affects or is affected by other medicines. Do not apply other medicines or treatments to your face at the same time as Skinoren Gel.

**Pregnancy and breast-feeding**

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.
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 Skinoren Gel.

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

**Driving and using machines**

Skinoren Gel has no influence on the ability to drive and use machines.

**Skinoren Gel contains benzoic acid and propylene glycol.**
Skinoren Gel contains 1 mg benzoic acid in each g. Benzoic acid may cause local irritation.

Skinoren Gel contains 120 mg propylene glycol in each g.

## 3. How to use Skinoren® Gel

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
Skinoren Gel is intended for external (cutaneous) use only.

***Method of administration***
Before you apply Skinoren Gel, 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.

***Usual dosage and frequency of administration***
Apply Skinoren Gel 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.

To achieve an optimal effect of the treatment it is important to use Skinoren Gel 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 Skinoren Gel 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***
The duration of use of Skinoren Gel 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 Skinoren Gel.

**Acne:** You can use Skinoren Gel 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 Skinoren Gel and consult your doctor.

**Rosacea:** You can use Skinoren Gel 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 Skinoren Gel and consult your doctor.

**If you use more Skinoren Gel than you should**

Even if you have accidentally used more Skinoren Gel 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 Skinoren Gel**

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

**If you stop using Skinoren Gel**

If you stop using Skinoren Gel your skin disease can get worse. Please ask your doctor before you stop using Skinoren Gel.

If you have any further questions on the use of Skinoren Gel, ask your doctor or pharmacist.

## 4. Possible side effects

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

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 (pruritus), burning and pain at the application site.
The following side effects may occur during the treatment with Skinoren Gel. They only concern the skin in the application area:

*Acne:*
**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):** 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]:** Hypersensitivity, which may occur with one or more of the following adverse reactions: Angioedema (rapid swelling under the skin), Eye swelling, Swelling face, Dyspnoea (shortness of breath)
- 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 (edema) 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]:** Hypersensitivity, which may occur with one or more of the following adverse reactions: Angioedema (rapid swelling under the skin), Eye swelling, Swelling face, Dyspnoea (shortness of breath)
- 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 Skinoren Gel was similar to that for the entire patient population.

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, website: www.hpra.ie

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

## 5. How to store Skinoren® Gel

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.

Skinoren Gel 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 Skinoren Gel contains

- The active substance is azelaic acid (Each gram of Skinoren Gel contains 150 mg of azelaic acid).
- The other ingredients are: Benzoic acid (E 210), carbomers, disodium edetate, lecithin, polysorbate 80, propylene glycol, purified water, sodium hydroxide and triglycerides medium chain.

### What Skinoren Gel looks like and contents of the pack

Skinoren Gel is a white to yellowish-white opaque gel.
Skinoren Gel 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

MA Holder:
LEO Pharma A/S
Industriparken 55
DK-2750 Ballerup
Denmark

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

**This medicinal product is authorised in the Member States of the EEA under the following names:**
Finacea: Denmark, France, Iceland, Italy, Norway, Spain, Sweden, United Kingdom.
Skinoren: Austria, Finland, Germany, Greece, Ireland, Portugal

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For information in large print, Braille or audio/CD,
telephone +353 (0) 1 4908924

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