

SKINOREN® CREAM

Azelaic acid (200 mg/g)

What is in this leaflet

1. What Skinoren® Cream is used for
2. How Skinoren® Cream works
3. Before you take Skinoren® Cream
4. How to take Skinoren® Cream
5. While you are using Skinoren® Cream
6. Side effects
7. Storage and Disposal of Skinoren® Cream
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

Keep this Leaflet. You may need to read it again.

What Skinoren® Cream is used for

- Skinoren is a skin cream used to treat acne.
- Do not use this medicine for any other skin condition.

How Skinoren® Cream works

- Skinoren attacks bacteria which cause acne.
- Skinoren also stops dead skin cells buildup which will block the pores of the skin to form pimples.

Before you use Skinoren® Cream

- When you must not use it
Do not use Skinoren® Cream:
 - If you are allergic to azelaic acid or any of the other ingredients of this medicine (listed under "Ingredients").
- Before you start to use it
 - Talk to your doctor or pharmacist before using Skinoren if you have asthma.
- Taking other medicine
 - Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

How to use Skinoren® Cream

- First thoroughly wash with plain water the whole area to be treated. If the skin is greasy use a mild skin cleanser. Dry the skin thoroughly and apply Skinoren gently. Wash

your hand thoroughly after using Skinoren.

- How much to use

- The amount of Skinoren you should use will depend on the size of the area to be treated:
 - o As a guide, if the whole of your face is affected, use 1 fingertip (approx. 0.5 g) of cream each time you apply Skinoren.
 - o If you have acne on your chest and back, as well as your face, adjust the amount of cream accordingly.
- Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- When to use it

- Unless your doctor has told you otherwise, start treatment with Skinoren twice a day (morning and evening).

- How long to use it

- Duration of Skinoren usage varies for every individual. It depends upon how bad your acne is when you start treatment. You should be able to see a distinct improvement after about 4 weeks. To get the best effect you will probably have to use Skinoren regularly for several months. However, you should not use Skinoren cream for more than 12 months at any one time.

- If you forget to use it

- Do not use increased amounts of Skinoren cream to make up for a dose(s) that you left out.

- If you use too much (overdose)

- Don't worry. No risk of poisoning had been reported from a one-time overdose (that is, when the cream is applied

once to a large skin area) or from accidental swallowing of the cream.

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

While you are using it

- Things you must do
 - Skinoren is for external use on the skin only.
 - Stop using Skinoren and see your doctor as soon as possible if you think you are having an allergic reaction (e.g. rash) to Skinoren.
 - Commonly local skin irritation occurs with Skinoren, usually at the start of treatment. In most cases the irritation is mild and usually gets better as treatment continues. **If skin irritation remains troublesome:**
 - o reduce the amount of Skinoren you apply each time
 - o or apply it only once a day
 - o or stop treatment temporarily

If skin irritation still persists, tell your doctor.

- Things you must not do

- Do not allow Skinoren to come into contact with your eyes, mouth or other mucous membranes. If it does, wash the eyes, mouth or other mucous membranes immediately with large amounts of cool water.

- Things to be careful of

Pregnancy and breast-feeding

- There is limited experience with use of the active substance azelaic acid during pregnancy. 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 using this medicine.

SKINOREN® CREAM

Azelaic acid (200 mg/g)

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

Important information about some of the ingredients of Skinoren® Cream

- Skinoren cream contains benzoic acid which is mildly irritating to the skin, eyes and mucous membranes.
- Skinoren contains propylene glycol which may cause skin irritation.

Possible side effects

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

The following side effects are based on reports from clinical studies and post-marketing surveillance with Skinoren Cream starting with the most frequent ones:

Very common (may affect more than 1 in 10 people):

- Burning
- Itching or abnormal redness of the skin at the site of application.

Common (may affect up to 1 in 10 people):

- Scaling
- Pain
- Dryness
- Skin discolouration or irritation at the site of application.

Uncommon (may affect up to 1 in 100 people):

- Scaly, red skin
- Acne or loss of skin colour
- Tingling
- Skin inflammation
- Discomfort or swelling at the site of application.

Rare (may affect up to 1 in 1,000 people):

- Lips inflammation
- Small blisters

- Eczema
- Ulceration
- Warmth at the site of application
- Allergic reaction

Not Known (frequency cannot be estimated from the available data)¹:

- Skin swelling
- Eye swelling
- Swelling face (which may occur with hypersensitivity)
- Rash
- Hives
- Worsening of asthma.

¹ These additional side effects have been reported in people using Skinoren Cream since this product is marketed.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

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

Storage and Disposal of Skinoren® Cream

- **Storage**
 - Keep out of the reach and sight of children.
 - Store below 30°C.
 - Do not use Skinoren® Cream after the expiry date which is stated on the box. The expiry date (month) refers to last day of the month.
 - After first opening of the container, the in-use shelf life is 6 months

Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

What it looks like

- Skinoren is a white cream.

Ingredients

- **Active ingredient:**
Azelaic acid. One gram of Skinoren Cream contains 200 mg (20% w/w) of azelaic acid.
- **Inactive ingredient:**
Benzoic acid, Cetearyl octanoate + Isopropyl myristate (PCL Liquid®), Glycerol 85%, Glyceryl monostearate 40-55, Cetostearyl alcohol, Propylene glycol, Purified Water, Arlatone 983 S

MAL number(s):

MAL20000036AZ

Manufacturer

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

Product Registration Holder

DKSH Malaysia Sdn Bhd,
B-11-01, The Ascent, Paradigm
No.1, Jalan SS7/26A, Kelana Jaya
47301 Petaling Jaya
Selangor Darul Ehsan

Date of revision

2 May 2023

Serial Number

NPRA (R1/2) 28042023/091