Package leaflet: Information for the patient 000000-XX

Skinoren® 20 % Cream

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

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

- Skinoren is a skin cream used to treat **common acne (acne vulgaris).**
- Skinoren Cream should only be used to treat acne. You should not use this medicine for any other skin condition.
- Skinoren attacks the bacterium called Propionibacterium acnes, which plays an essential part in causing acne. Skinoren also reduces growth of the harder outermost skin cells that block the pores of the skin to cause blackheads and whiteheads.

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

Do not use Skinoren
- 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 Skinoren.

Skinoren is for external use on the skin only. You should 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.

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

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

Other medicines and Skinoren
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

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 taking this medicine.

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

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

Skinoren contains benzoic acid
Benzoic acid is mildly irritating to the skin, eyes and mucous membranes. Skinoren contains a very small amount of this ingredient.

Skinoren contains propylene glycol
Propylene glycol may cause skin irritation.

3. How to use Skinoren®

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

Adults and Adolescents (12 - 18 years of age)
- 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 before applying Skinoren.
- Unless your doctor has told you otherwise, **start treatment with Skinoren twice a day.**
- **If your skin is very sensitive** use Skinoren once a day, in the evening during the first week of treatment. Then change to twice a day.
- **The amount of Skinoren you should use will depend on the size of the area to be treated:**
  - As a guide, if the whole of your face is affected, use 2.5 cm (approx. 0.5 g) of cream each time you apply Skinoren.
  - If you have acne on your chest and back, as well as your face, adjust the amount of cream accordingly.

Use the cream regularly. Rub it in gently.

Wash your hands thoroughly after using Skinoren.

How long Skinoren has to be used varies from person to person. It depends upon how bad your acne is when you start treatment. You should 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 for more than 12 months at any time.**

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

4. Possible side effects

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

Reasons to stop using Skinoren
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.

Occasionally 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:
- reduce the amount of Skinoren you apply each time
- or apply it only once a day
- or stop treatment temporarily.

If skin irritation still remains troublesome tell your doctor.

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 (erythema) 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): greasy skin, acne or loss of skin colour, tingling, dermatitis, discomfort or swelling at the site of application.

Rare (may affect up to 1 in 1,000 people): cracking of the lips, vesicles (small blisters), eczema, ulceration, warmth at the site of application, allergic reaction, rash at the site of application.

Not Known (cannot be estimated from the available data)[1]: skin swelling, eye swelling, swelling face (which may occur with hypersensitivity), rash, urticaria, worsening of asthama.

[1] These additional side effects have been reported in patients using Skinoren Cream (frequency unknown) since marketing approval.

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 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 Skinoren®
- **Keep this medicine out of the sight and reach of children.**
- Store Skinoren below 30°C.
- Do not use this medicine after the expiry date which is stated on the box after EXP.
- After first opening of the container, the in-use shelf life is 6 months.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information
What Skinoren contains
- The active substance is azelaic acid. One gram of Skinoren Cream contains 200 mg (20% w/w) of azelaic acid.
- The other ingredients are: Benzoic acid (E210), cetearyl octanoate + isopropyl myristate (PCL Liquid®), glycerol 85%, glyceryl stearate + cetearyl alcohol + cetyl palmitate + cocoglycerides (CUTINA CBS), propylene glycol, purified water, stearoyl macrogolglycerides.

What Skinoren looks like and contents of the pack
Skinoren is a white opaque cream. Skinoren is available in tubes containing 20, 30 or 50 g. Not all pack sizes are marketed.

Marketing Authorisation Holder
LEO Laboratories Limited,
Hurley, Berkshire SL6 6RJ, UK

Manufacturer
LEO Pharma Manufacturing Italy S.r.l.
Via E. Schering 21, 20090 Segrate (Milan), Italy

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For information in large print, Braille or audio/CD, telephone +44 (0)1844 347333

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