

Package leaflet: Information for the user**Skinoren 20% w/w 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 contains the active substance azelaic acid

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 product for any other skin condition.

Skinoren attacks the bacteria called *Propionibacterium acnes*, which play an essential part in causing acne. Skinoren also reduces growth of the keratin surface 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 (hypersensitive) 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 Cream.

Skinoren should not be used by children.

Skinoren Cream is for external use on the skin only. Take care to avoid contact with the eyes, mouth and other mucous membranes or open wounds. 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 Cream.

Some patients with asthma have reported worsening of their symptoms after treatment with azelaic acid.

Other medicines and Skinoren Cream

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

It has not been studied whether Skinoren Cream affects or is affected by other medicines. Do not apply other medicines or treatments to your face at the same time as Skinoren Cream.

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 using 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 Cream.

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

Driving and using machines

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

Skinoren contains benzoic acid and propylene glycol

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

Propylene glycol: may cause skin irritation.

3. How to use Skinoren

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

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.

Skinoren should be applied to the affected areas of skin twice a day (morning and evening) and rubbed gently into the skin.

In case of excessive irritation of the skin (see “Undesirable effects”), you may temporarily use Skinoren only once a day or interrupt the treatment for a few days if required.

Use the cream regularly. Rub it in well. 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.

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

4. Possible side effects

Like all medicines, Skinoren Cream 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 redness at the application site.

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

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

Common (may affect up to 1 in 10 people): Pain, rash, irritation, skin discolouration, dry or flaky skin at the application site,

Uncommon (may affect up to 1 in 100 people): Feeling of tingling or numbness (paraesthesia), skin reaction due to an external agent (contact dermatitis), scaling, warmth, skin whitening, discomfort or swelling at the application site, acne, red, itchy and scaly skin (seborrhoea)

Rare (may affect up to 1 in 1,000 people): allergic reaction (hypersensitivity), worsening of asthma

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. 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.

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

Skinoren Cream 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 you no longer use. These measures will help 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%) of azelaic acid).
- The other ingredients are: Stearoyl Macroglycerides, Cutina CBS (glyceryl stearate, cetearyl alcohol, cetyl palmitate, cocoglycerides), Cetearyl octanoate, propylene glycol, glycerol 85%, benzoic acid (E210), purified water.

What Skinoren looks like and contents of the pack

Skinoren is available in tubes of 30 g.

Marketing Authorisation Holder

Bayer Limited
The Atrium
Blackthorn Road
Dublin 18

Manufacturer:

Bayer HealthCare Manufacturing S.r.l.,
Via E. Schering 21,
20090 Segrate,
Milan,
Italy.

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