

PATIENT INFORMATION LEAFLET

Skinoren® 20% Cream

Azelaic acid



Read all of this leaflet carefully before you start using this medicine.

- ▶ 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- ▶ If you experience any side effect and this becomes serious, tell your doctor or pharmacist.

ingredients of Skinoren Cream. These are listed in section 6, "Further Information".

Take special care with Skinoren

Skinoren is for external use on the skin only. You should not allow Skinoren to come into contact with your eyes. If it does, bathe your eyes immediately with large amounts of cool water.

Taking other medicines

Please tell your doctor or pharmacist if you are using or have recently used any other medicines, including medicines obtained without a prescription.

In this leaflet:

1. What Skinoren is and what it is used for

2. Before you use Skinoren

3. How to use Skinoren

4. Possible side effects

5. How to store Skinoren

6. Further 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 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 harder outermost skin cells that block the pores of the skin to cause blackheads and whiteheads.

2. Before you use Skinoren

Do not use Skinoren:

If you are allergic (hypersensitive) to azelaic acid, propylene glycol or any of the other

Pregnancy and breast-feeding

You should not use Skinoren if you are pregnant or breast-feeding without discussing it with your doctor first.

Ask your doctor or pharmacist for advice before taking any medicine.

Important information about some of the ingredients of Skinoren

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. You should 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.
- ▶ 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.



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► **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 1 g (4 cm length) each time you apply Skinoren.
- If you have acne on your chest and back, as well as your face, do not use more than 10 g (40 cm length) of cream each day.

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. **However, you should not use Skinoren for more than 6 months at any time.**

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

4. Possible side effects

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. Very rarely, allergic-type skin reactions may occur.

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

Occasionally local skin irritation occurs with Skinoren, usually at the start of treatment. This includes reddening, dry and flaky skin, itching or burning of the skin. 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.

Very rarely, abnormal reactions of the skin to sunlight (photosensitivity reactions) have been reported by patients using Skinoren.

If you experience any of these side effects and this becomes serious, or if you notice

any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Skinoren

► **Store Skinoren Cream out of the reach and sight of children.**

- Store Skinoren below 30°C.
- Do not use Skinoren after the expiry date which is printed on the box.
- Medicines must 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.

6. Further 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: Arlatone 983S (polyoxyethylene fatty acid ester), cutina CBS (mixture of mono-diglyceridene, fatty alcohols, triglycerides and wax esters), cetearyl octanoate, propylene glycol, glycerol 85% (E 422), benzoic acid (E 210), purified water.

What Skinoren looks like and contents of the pack

Skinoren is available in tubes containing 20, 30 or 50 g. Not all pack sizes are marketed.

Marketing Authorisation Holder

Intendis GmbH, Max-Dohrn-Strasse 10, D-10589, Berlin, Germany.

Manufacturer

Intendis Manufacturing, S.p.A, Milan, Italy.


Distributor in the UK

Bayer plc, Bayer House, Strawberry Hill, Newbury, Berkshire, RG14 1JA. United Kingdom.

This leaflet was last approved in February 2010

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Great Britain 82684477

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