



INTENDIS

Skinoren® cream

(Azelaic acid)

Read all of this leaflet carefully before you start taking the medicine

- Keep this leaflet. You may need to read it again
- If you have further questions, please ask your doctor or your pharmacist
- Skinoren has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

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

The name of your medicine is Skinoren. It is a cream for use on the skin.

The active ingredient in Skinoren is 20% azelaic acid in an oil-in-water emulsion. The cream also contains arlatone 983S, cutina CBS, cetearyl octanoate, propylene glycol, glycerol 85% (E 422), benzoic acid (E 210) and purified water. Skinoren is supplied in 30 g tubes.

The marketing authorisation holder for Skinoren cream is Intendis GmbH, Max-Dohrn-Straße 10, 10589 Berlin, Germany. The distributor in the UK is Valeant Pharmaceuticals Ltd, Cedarwood, Chineham Business Park, Crockford Lane, Basingstoke, Hampshire, RG24 8WD, UK. It is manufactured by Intendis Manufacturing S.p.A., Milan, Italy.

What is Skinoren used for?

Skinoren is used to treat all stages of common acne (acne vulgaris).

How does Skinoren work?

Skinoren attacks the bacteria, *Propionibacterium acnes*, that 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. Before you use Skinoren

Do not use Skinoren if:

- you are allergic or hypersensitive to propylene glycol or to any of the other ingredients in Skinoren.

What you should know before you use Skinoren

Skinoren is for topical use only. This means that it is put on the skin. 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.

Can Skinoren be used during pregnancy and breast-feeding?

You should not use Skinoren if you are pregnant or

breast-feeding. Its use in these circumstances has not been studied.

Important information about some of the ingredients of Skinoren

Skinoren contains a very small amount of benzoic acid. Benzoic acid is mildly irritating to the skin, eyes and mucous membrane. Skinoren also contains propylene glycol, which may cause skin irritation.

3. How to use Skinoren

First wash thoroughly 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, morning and evening. 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, morning and evening.

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 4 cm of cream (1 g) 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 of cream each day.

Use the cream regularly. Rub it in well. Wash your hands thoroughly after using Skinoren.

How long will Skinoren take to work?

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.

You should not use Skinoren for more than 6 months.

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IF YOU HAVE ANY FURTHER QUESTIONS PLEASE ASK YOUR DOCTOR OR PHARMACIST

4. Possible undesirable effects

Like all medicines, Skinoren may have undesirable effects.

Occasionally local skin irritation occurs with Skinoren, usually at the start of treatment. This includes reddening, scaling, 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.

Very rarely, allergic-type skin reactions (e.g. rash) may also occur (see "Do not use Skinoren if").

You should tell your doctor about any change in your health or general sense of well-being that you notice while using Skinoren.

5. Storing Skinoren

Keep Skinoren out of the reach and sight of children.

Do not store above 30°C.

Do not use the cream after the expiry date which is printed on the box.

