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Due to regulatory changes, the content of the following Patient Information Leaflet may vary from the one found in your medicine pack. Please compare the 'Leaflet prepared/revised date' towards the end of the leaflet to establish if there have been any changes.

If you have any doubts or queries about your medication, please contact your doctor or pharmacist.



**PATIENT INFORMATION LEAFLET**

**Skinoren<sup>®</sup> 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.

**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**
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**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 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. Before you use Skinoren**

### **Do not use Skinoren:**

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

### **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.

### **Pregnancy and breast-feeding**

There is limited experience with use of the active substance azelaic acid during pregnancy. If you are pregnant or breastfeeding, your doctor will decide whether you can still use Skinoren. Infants must not come into contact with treated skin or breast.

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

### **Driving and Using Machines**

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

### **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.**

### **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 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.

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. 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 reported side effects are listed below, based on the following frequency scheme:  
Very common: affects more than 1 user in 10.

Common:	affects 1 to 10 users in 100.
Uncommon:	affects 1 to 10 users in 1,000.
Rare:	affects 1 to 10 users in 10,000.
Very rare:	affects less than 1 user in 10,000.
Not known:	frequency cannot be estimated from the available data.

Very common: burning, itching or abnormal redness of the skin (erythema) at the site of application.

Common: scaling, pain, dryness, skin discolouration or irritation at the site of application.

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

Rare: cracking of the lips, vesicles (small blisters), eczema, ulceration, warmth at the site of application, allergic reaction, rash at the site of application, worsening of asthma symptoms.

**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% w/w) of azelaic acid.
- The other ingredients are: Arlatone 983S (polyoxyethylene fatty acid ester), cutina CBS (mixture of mono-diglycerides, fatty alcohols, triglycerides and wax esters), cetearyl octanoate, propylene glycol, glycerol 85% (E422), benzoic acid (E210), purified water.

### 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

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, RG 14 1JA, United Kingdom.

**This leaflet was last revised in February 2013.**

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