PATIENT INFORMATION LEAFET

SCHEDULING STATUS

S1

SKINOREN ACNE CREAM 200 mg (20 % *w/w*) azelaic acid

Azelaic acid

Read all of this leaflet carefully because it contains important information for you

SKINOREN ACNE CREAM is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use SKINOREN ACNE CREAM carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share SKINOREN ACNE CREAM with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 4 weeks.

What is in this leaflet

1. What SKINOREN ACNE CREAM is and what it is used for

2. What you need to know before you use SKINOREN ACNE CREAM

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1. What SKINOREN ACNE CREAM is and what it is used for

SKINOREN ACNE CREAM attacks the bacteria called *Propionibacterium acnes*, which plays an essential part in causing acne. SKINOREN ACNE CREAM also reduces growth of the harder outermost skin cells that block the pores of the skin to cause blackheads and whiteheads.

SKINOREN ACNE CREAM is used for the treatment of mild to moderate acne.

2. What you need to know before you use SKINOREN ACNE CREAM

Do not use SKINOREN ACNE CREAM:

- If you are hypersensitive to azelaic acid or any of the ingredients of SKINOREN ACNE CREAM.
- Safety in pregnancy and breastfeeding has not been established.

Warnings and precautions

Take special care with SKINOREN ACNE CREAM:

SKINOREN ACNE CREAM is for external use only.

- Care must be taken to prevent SKINOREN ACNE CREAM from coming into contact with the eyes or mouth. If it does, the eyes or mouth should immediately be thoroughly rinsed with water. If eye irritation persists, you should consult a doctor. Your hands should be washed after each application of SKINOREN ACNE CREAM.
- If you suffer from asthma (worsening of your asthma can occur).
- Benzoic acid is irritant to the skin, eyes and mucous membrane.
- Propylene glycol may cause skin irritation.

Children and adolescents

SKINOREN ACNE CREAM can be used in adolescents (12 to 18 years of age). Safety in children below the age of 12 years has not been established.

Other medicines and SKINOREN ACNE CREAM

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

There are no interactions so far known for SKINOREN ACNE CREAM.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult

your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

Safety in pregnancy and breastfeeding has not been established.

Driving and using machines

SKINOREN ACNE CREAM has no influence on the ability to drive and use machines.

SKINOREN ACNE CREAM contains benzoic acid and propylene glycol

Benzoic acid and propylene glycol may cause local irritation to your skin.

3. How to use SKINOREN ACNE CREAM

Do not share medicines prescribed for you with any other person.

Always use SKINOREN ACNE CREAM exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you. Check with your doctor, pharmacist or nurse if you are not sure.

- Before SKINOREN ACNE CREAM is applied, the skin should be thoroughly cleaned with plain water and dried. A mild skin-cleansing agent may be used.
- SKINOREN ACNE CREAM should be applied to the affected skin areas twice a day (morning and evening) and rubbed gently into the skin.
- The amount of SKINOREN ACNE CREAM to be applied will depend on the size of the affected area.
- In the event of intolerable irritation of the skin (see section 4), the amount of SKINOREN ACNE CREAM per application should be reduced or the frequency of use of SKINOREN ACNE CREAM should be reduced to once a day until the irritation ceases. If required, the treatment should be temporarily interrupted for a few days.
- The duration of use of SKINOREN ACNE CREAM can vary from person to person and also depends on the severity of the skin disorder. In general, an improvement becomes apparent after about 4 weeks. To obtain the best results, however, SKINOREN ACNE CREAM should be used continuously over several months.
- There is clinical experience for a continuous application time period up to one year.

If you use more SKINOREN ACNE CREAM than you should or if SKINOREN ACNE CREAM is taken

by mouth

In the event of an overdosage, consult your doctor or pharmacist. If neither is available, rush the patient to the nearest hospital or poison control centre.

4. Possible side effects

SKINOREN ACNE CREAM can have side effects.

If any of the following happens, stop using SKINOREN ACNE CREAM and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting

These are all very serious side effects. If you have them, you may have had a serious reaction to SKINOREN ACNE CREAM. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Application site burning
- Application site itching, irritable skin
- Application site erythema (skin rash)
- Application site exfoliation (removal of dead skin)
- Application site pain
- Application site dryness
- Application site discolouration
- Application site irritation.

Less frequent side effects:

- Sensation of tingling, burning, pricking or numbness of skin at the application site

- Application site dermatitis (inflamed, irritated skin)
- Application site discomfort
- Application site oedema (swelling of the skin)
- Seborrhoea (excessively oily skin)
- Worsening of acne
- Skin depigmentation (skin colour blotches)
- Inflammation and cracking of lips
- Application site vesicles (small fluid-filled sacks/blisters on the skin)
- Application site eczema (dry, red, itchy and bumpy skin)
- Application site warmth
- Application site ulcer (open sore or wound)

Local skin irritation (mostly burning or itching sensations, reddening and scaling) may occur, usually at the start of treatment.

Cases of worsening of asthma have been reported.

Not all side effects reported for SKINOREN ACNE CREAM are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using SKINOREN ACNE CREAM, please consult your doctor, pharmacist or other healthcare professional for advice.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of SKINOREN ACNE CREAM.

5. How to store SKINOREN ACNE CREAM

Keep SKINOREN ACNE CREAM out of the reach of children.

Store at or below 30 °C. Keep well closed.

In-use stability of 6 months.

Do not use after the expiry date stated on the pack.

Return all unused medicine to your pharmacist for safe disposal.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What SKINOREN ACNE CREAM contains

The active substance is Azelaic acid. 1 gram SKINOREN ACNE CREAM contains 200 mg azelaic acid (20 % *w/w*).

The other ingredients are arlatone 983 S; cetostearyl alcohol; PCL liquid; propylene glycol; glycerol 85 %; glycerol monostearate 40-55; purified water and benzoic acid (0,2 % *w/w*) as a preservative.

What SKINOREN ACNE CREAM looks like and contents of the pack

White to slightly yellowish opaque cream.

Tubes of 10, 20, 30 or 50 g. The tubes are made of aluminium and screw cap are made of high density polyethylene.

Holder of the Certificate of Registration

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This leaflet was last revised in

25 May 2022

Registration number

South Africa: W/13.12/228

Namibia: 04/13.12/1438

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