

SKINOREN[®] CREAM

Azelaic acid (A-zel-ae-ic acid)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Skinoren Cream. It does not contain all the available information.

It does not take the place of talking to your doctor (or pharmacist).

All medicines have benefits and risks. Your doctor or pharmacist has weighed the risks of you using Skinoren Cream against the benefits they expect it will have for you.

If you have any concerns about this medicine, ask your doctor or pharmacist.

Keep this leaflet with your medicine. You may need to read it again.

What is Skinoren Cream used for and how does it work?

Skinoren Cream is used to treat the following conditions:

Topical treatment of acne vulgaris, usually simply called acne. When rubbed into the skin, the azelaic acid in Skinoren Cream kills the bacteria that cause acne. In addition, Skinoren Cream stops the acne-relevant (epidermal) skin cells from growing too strongly and thus blocking the pores of the skin to form pimples.

There is no evidence that Skinoren Cream is addictive.

Before you use Skinoren Cream

When you must not use it

Do not use Skinoren Cream if:

- **you have an allergy to:** Skinoren Cream or any of the ingredients in Skinoren Cream listed at the end of this leaflet, in particular propylene glycol.

Skinoren Cream is for external use only.

You should be careful not to get Skinoren Cream in your eyes when putting it onto your face.

The absorption of Skinoren Cream into the blood stream is very limited.

Do not use Skinoren Cream just before having a bath, shower or going swimming.

If you do, you may reduce the effectiveness of Skinoren Cream.

Using other medicines and skin treatments

There is no information available on the use of Skinoren Cream in conjunction with other skin disorder treatments, sunscreens or cosmetics.

Do not use Skinoren Cream if the packaging is torn or shows signs of tampering.

Do not use Skinoren Cream if the expiry date (EXP) printed on the pack has passed.

If you use this medicine after the expiry date has passed, it may not work (or work as well).

If you are not sure whether you should start using Skinoren

Cream, contact your doctor or pharmacist.

Before you start to use it

Tell your doctor or pharmacist if:

1. **you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.**
2. **you are pregnant or intend to become pregnant.**
Your doctor or pharmacist will discuss the risks and benefits of using Skinoren Cream when pregnant.
3. **you are breastfeeding or intend to breastfeed.**
Your doctor or pharmacist will discuss the risks and benefits of using Skinoren Cream when breastfeeding.

If you have not told your doctor or pharmacist about any of the above, tell them before you use any Skinoren Cream.

How to use Skinoren Cream

How much to use

Skinoren Cream should be applied to the affected areas of the skin twice a day (morning and night), and should be used regularly over several months. This dosage may be modified by your doctor or pharmacist.

Use of Skinoren Cream more than twice daily will not increase its effectiveness, and could cause irritation.

Skinoren Cream should be massaged into the skin gently until it absorbs.

Skinoren Cream should be applied sparingly; (approximately 0.5 g, equivalent to a 2.5 cm strip of Cream is sufficient for the entire facial area).

How to use it

Before Skinoren Cream is applied, the skin should be thoroughly cleaned with water, or with a mild skin-cleansing agent.

Be careful not to get Skinoren Cream in your eyes when putting it on your face. Skinoren Cream is very irritating to the eyes. If Skinoren Cream is accidentally rubbed into your eye, you should immediately rinse your eye with large amounts of water.

How long to use it

The length of time that Skinoren Cream needs to be used will vary from person to person, and will also depend on the initial severity of your skin disorder. Improvement is usually noticed within 1–2 months of use, but to obtain the best results, Skinoren Cream should be used regularly over several months. Whilst in most cases you will not need to use Skinoren Cream for more than 6 months, it may be used for longer periods, and may also be re-used after a period of stopping.

If intolerable irritation of the skin develops (see **Side effects**), treatment should be stopped immediately. If irritation persists, please see your doctor or pharmacist. Once the irritation has ceased, your pharmacist or doctor may advise you to recommence treatment using a smaller amount of Cream or using the Cream only once a day until the skin can tolerate the treatment.

If your condition does not improve within 8 weeks you should consult your doctor or pharmacist.

If you forget to use it

If you forget to use Skinoren Cream, use it as soon as you remember. Then go on as before. If you are not sure what to do, ask your doctor or pharmacist.

If you use too much (overdose) or if you swallow it

Immediately telephone your doctor or the New Zealand Poisons Information Centre on 0800 764 766, if you think that you or anyone else may have used too much or swallowed Skinoren Cream. Do this even if there are no signs of discomfort or poisoning. Keep this telephone number handy.

While you are using Skinoren Cream

Things you must do

Tell all doctors and pharmacists who are treating you that you are using Skinoren Cream.

If you feel that Skinoren Cream is not helping your condition, tell your doctor (or pharmacist).

Tell your doctor or pharmacist if, for any reason, you have not used Skinoren Cream exactly as prescribed.

Otherwise, your doctor or pharmacist may think that it was not effective and change your treatment unnecessarily.

If you become pregnant while using Skinoren Cream, tell your doctor.

Things you must not do

Do not use Skinoren Cream in or near the eyes.

Do not give Skinoren Cream to anyone else, even if they have the same symptoms as yours.

Do not use Skinoren Cream to treat other complaints unless your doctor or pharmacist tells you to.

Side effects

Tell your doctor or pharmacist if you do not feel well while you are using Skinoren Cream.

Like other medicines, Skinoren Cream can cause some side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- burning
- itching
- stinging/tingling
- redness
- skin dryness
- skin scaling

These are the more common side effects of Skinoren Cream and can occur at the start of treatment. When treating acne, they usually disappear as treatment continues. Skin disease, acne and hair infections are uncommon. If marked skin irritation persists, the treatment should be stopped until the irritation goes, and you should ask your doctor or pharmacist before recommencing.

Topical azelaic acid preparations may rarely cause temporary skin depigmentation or skin discolouration especially in people with darker skin.

In very rare cases allergic skin reaction (e.g. rash) may occur.

Some people may get other side effects while using Skinoren Cream.

Ask your doctor or pharmacist if you don't understand anything in this list.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using Skinoren Cream

Storage

Keep Skinoren Cream in a cool dry place where the temperature stays below 30°C. Do not store

Skinoren Cream or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep Skinoren Cream where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor or pharmacist tells you to stop using Skinoren Cream or it has passed its expiry date, ask your pharmacist what to do with any that is left over.

Product description

Skinoren Cream is the brand name for a cream containing 20% azelaic acid. It also contains benzoic acid, propylene glycol, Cutina CBS (mixture of mono-diglyceridene, fatty alcohols, triglycerides and wax esters), Arlatone 983S, glycerol, cetearyl octanoate and water.

Skinoren Cream is a white to slightly yellowish opaque cream.

Skinoren Cream is available in 30 g tubes.

Skinoren® is sponsored in New Zealand by:

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