

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Finacea®.

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 Finacea® 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 Finacea® is used for

Finacea® is used to treat the following conditions:

- Mild to moderate acne vulgaris, usually simply called acne
- Rosacea, where the skin on the nose and cheeks has one or more of the following features: a redness that looks like a blush; pimples; small knobby lumps on the nose and / or thin red lines due to enlarged blood vessels.

If using Finacea® for rosacea, you should contact a doctor for a correct diagnosis of your condition before commencing treatment.

When rubbed into the skin, the azelaic acid in Finacea® kills the bacteria that cause acne. In addition Finacea® stops the acne relevant (epidermal) skin cells from growing too strongly and thus blocking the pores of the skin to form pimples.

It is not known exactly how Finacea® works to treat rosacea.

Finacea® has been especially formulated for use in acne patients with greasy skin conditions.

There is no evidence that Finacea® is addictive.

Before you use Finacea®

When you must not use it

Do not use Finacea® if:

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

Finacea® is for external use only.

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

The absorption of Finacea® into the blood stream is very limited.

Do not use Finacea® just before having a bath, shower or going swimming.

If you do, you may reduce the effectiveness of Finacea®.

Using other medicines and skin treatments.

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

Do not use Finacea® if the packaging is torn or shows signs of tampering.

Do not use Finacea® 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 (as well).

If you are not sure whether you should start using Finacea®, contact your doctor or pharmacist.

Before you start to use it

Tell your doctor or pharmacist if:

1. **if you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.**

Pregnancy and breast-feeding:

2. **if you are pregnant or intend to become pregnant**

Your doctor or pharmacist will discuss the risks and benefits of using Finacea® when pregnant.

3. **if you are breast-feeding or intend to breast-feed**

Your doctor or pharmacist will discuss the risks and benefits of using Finacea® when breast-feeding.

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

How to use Finacea®

How much to use

Finacea® should be applied to the affected areas of the skin morning and night, and should be used regularly over several months. This dosage may be modified by your doctor or pharmacist.

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

Finacea® should be massaged into the skin gently until it vanishes.

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

How to use it

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

Be careful not to get Finacea® in your eyes when putting it on your face. Finacea® is very irritating to the eyes. If Finacea® 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 Finacea® 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, Finacea® should be used regularly over several months. Whilst in most cases you will not need to use Finacea® for more than 6 months, it may be used for longer periods, and may also be reused 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 gel or using the gel 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 Finacea®, 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 Poisons Information Centre (telephone 11 26), if you think that you or anyone else may have swallowed Finacea®. Do this even if there are no signs of discomfort or poisoning. Keep this telephone number handy.

While you are using Finacea®

Things you must do

Tell all doctors and pharmacists who are treating you that you are using Finacea®.

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

Tell your doctor or pharmacist if, for any reason, you have not used Finacea® 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 Finacea®, tell your doctor.

Things you must not do

Do not use Finacea® in or near the eyes.

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

Do not use Finacea® 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 Finacea®.

Like other medicines, Finacea® 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 Finacea® 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.

The occurrence of side effects was higher in rosacea patients compared to acne patients in the clinical trials, however this could be due to the more sensitive skin of rosacea patients.

Some people may get other side effects while using Finacea®.

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 Finacea®

Storage

Keep Finacea® in a cool dry place where the temperature stays below 30°C.

Do not store Finacea® 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 Finacea® 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 Finacea® or it has passed its expiry date, ask your pharmacist what to do with any Finacea® that is left over.

Product description

Finacea® is the brand name for a gel containing 15% azelaic acid. It also contains benzoic acid, propylene glycol, polysorbate 80, lecithin, polyacrylic acid, medium chain triglycerides, sodium hydroxide, disodium edetate and purified water.

Finacea® is available in 5g, 30g and 50g tubes. Not all pack sizes may be available.

Its AUST R number is 97747

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Sponsor

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