

Package leaflet: information for the user

ketoconazol cinfa 2% gel

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What ketoconazol cinfa is and what it is used for
2. What you need to know before you start using ketoconazol cinfa
3. How to use ketoconazol cinfa
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1. What ketoconazol cinfa is and what it is used for

Ketoconazol belongs to the group of medicines known as antifungals (medicines used to treat infections with fungi and yeast).

This medicine is indicated in adolescents and adults for the treatment and prevention of the following skin infections caused by fungi and yeast.

- Seborrhoeic dermatitis, a condition that affects mainly the face and chest and cause skin reddening and flaking.
- *Pytirtiasis capitis* (dandruff), characterised by flaking of the scalp.
- *Pytirtiasis versicolor*, condition characterised by the onset of small irregular areas, brownish or whitish, distributed along the core.

2. What you need to know before you start using ketoconazol cinfa

Do not use ketoconazol cinfa:

if you are allergic to the active substance or any of the other ingredients of this medicine (listed in section 6).

After application, some symptoms of allergy may be itching and irritation.

Warnings and precautions

Talk to your doctor or pharmacist before using ketoconazol cinfa.

- If you are undergoing treatment with corticosteroid cream, inform your doctor or pharmacist before starting the treatment. You can start your treatment with this medication, but you must not discontinue the application suddenly, your skin might have a reaction and develop reddening or itching.

Continue your treatment with corticosteroids as instructed below:

- apply the same amount during the first week,
- decrease the frequency gradually throughout the second to third week,
- completely stop using corticosteroids.

In the event of allergic reaction, discontinue the treatment and go see your doctor immediately.

- Only for external use. Avoid contact with the eyes. If it happened, wash your eyes with water and if necessary, talk to a dermatologist.

Children

The efficacy and safety of ketoconazol in children has not been evaluated.

Other medicines and ketoconazol cinfa

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

As a preventive measure, it is better to not use this medicine during pregnancy and breast-feeding, although there are no known associated risks of this medicine during pregnancy and breast-feeding.

Driving and using machines

The influence of this medicine on the ability to drive and operate machines is non-existent or negligible.

3. How to use ketoconazol cinfa

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose for this medicine will depend on the type of infection and whether you want to treat it or prevent it.

- For the treatment of *pityriasis versicolor*, apply it once a day for 5 days. For prevention, apply one single course once a day for 3 days in a row each year before summer.
- For the treatment of seborrhoeic dermatitis and *pityriasis capitis* (dandruff), apply twice a week for 2-4 weeks in a row. To prevent relapses after treatment, you can use it once every 1 or 2 weeks.

If no improvement is seen after 4 weeks of treatment, talk to a doctor.

Elderly patients

The dosage is the same as in adults.

Method of administration: Topical use.

ketoconazol cinfa can be applied both on the scalp and larger areas of the chest and face.

Wash the infected areas of the skin or the scalp allowing the medicine to act for 3 to 5 minutes before washing it off. Make sure to wash both your skin and your hair.

If you use more ketoconazol cinsa than you should

Do not ingest this medicine. In the event of accidental ingestion, contact your doctor. To prevent aspiration, do not provoke vomiting or perform gastric lavage.

In case of overdose or accidental ingestion, notify your doctor or pharmacist immediately or call the hospital, specifying the medicine and the amount ingested.

If you forget to use ketoconazol cinsa

Do not take a double dose to make up for a forgotten dose.

If you stop using ketoconazol cinsa

Your doctor will inform you of the duration of treatment with ketoconazol. Do not stop the treatment without talking to your doctor first, as your symptoms might reappear or worsen.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Uncommon side effects (may affect up to 1 in 100 patients)

- Inflammation of hair follicles
- Increased tearing
- Hair loss
- Dry skin
- Changes in hair texture
- Rash
- Burning sensation on the skin
- Reddened skin
- Skin irritation
- Itching on the application site
- Reaction on the application site

Rare side effects (may affect up to 1 in 1,000 patients)

- Allergic reaction (hypersensitivity)
- Distorted sense of taste
- Eye irritation
- Acne
- Localised eczema
- Sensitive skin
- Skin flaking
- Allergic reaction (hypersensitivity) on the application site
- Zits containing pus (pustules)

Frequency not known (frequency cannot be estimated from the available data):

- Sudden swelling of the skin or the mucous membranes, usually on the face, eyes or lips
- Changes in hair colour
- Urticaria

Stop the treatment in the event of intolerance to the gel.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. How to store ketoconazol cinfa

Keep this medicine out of reach and sight of children.

Please store below 25°C.

Shelf life: Do not use **ketoconazol cinfa[®] 2% gel** after the expiry date stated on the package.

THIS IS A PRESCRIPTION MEDICINE.

This patient leaflet was approved in May 2004.

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