

Package Leaflet: Information For The User

Ketoconazol-ratiopharm 20 mg/ml, shampoo ketoconazole

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

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice
- 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.
- You must talk to a doctor if your symptoms worsen or do not improve.

What is in this leaflet

1. What Ketoconazol ratiopharm is and what it is used for
2. What you need to know before you use Ketoconazol ratiopharm
3. How to use Ketoconazol ratiopharm
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1. What Ketoconazol ratiopharm is and what it is used for

Ketoconazol ratiopharm contains ketoconazole, which is an active substance intended for the treatment of infections caused by yeast and other fungi. The shampoo can be used for the treatment of the scalp.

Indications for use:

Ketoconazol ratiopharm shampoo is intended for the treatment of different skin infections caused by yeast and other fungi. Such infections can be recognized based on the following symptoms:

- scaling of the scalp (dandruff)
- reddish-brown, scaling patches in the scalp (seborrheic dermatitis of the scalp).

The above mentioned inflammations can be treated and prevented by the use of Ketoconazol ratiopharm shampoo.

2. What you need to know before you use Ketoconazol ratiopharm

Do not use Ketoconazol ratiopharm:

If you are allergic to ketoconazole or any of the other ingredients of this medicine (listed in section 6). Symptoms of hypersensitivity include itching and redness of the skin.

Warnings and precautions:

Avoid getting any shampoo into your eyes. Should this, however, happen, please rinse your eyes with water.

The most common indications of Ketoconazol ratiopharm, *i.e.* seborrheic eczema and scaling of the scalp, are often associated with hair loss also during the treatment with Ketoconazol ratiopharm.

Other medicines and Ketoconazol ratiopharm

Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicine.

If the skin area is being treated with corticosteroids, and this treatment is about to be ceased, it is recommended to withdraw that treatment gradually during a period of 2-3 weeks in order to prevent the skin symptoms from worsening. The use of Ketoconazol ratiopharm can already be started during this period of time.

Ask your doctor or pharmacist for further advice, if necessary.

Pregnancy, breast-feeding and fertility

Ketoconazol ratiopharm can be used during pregnancy and breast-feeding. There are no known risks connected to a use during pregnancy or breast-feeding.

Driving and using machines

Ketoconazol ratiopharm does not affect the user's ability to manage in traffic or to use equipment requiring accuracy.

Ketoconazole-ratiopharm contains a fragrance

With α -isomethylionone, benzyl alcohol, benzyl benzoate, benzyl cinnamate, citral, citronellol, coumarin, eugenol, farnesol, geraniol, hexyl cinnamon, isoeugenol, linalool, which may cause allergic reactions.

Ketoconazole-ratiopharm contains sodium laurilsulfate

This medicine contains 100 mg of sodium laurilsulfate per ml of shampoo.

Sodium lauryl sulphate may cause local skin reactions (eg tingling or burning sensation) or exacerbate skin reactions caused by other medicines in the same area.

3. How to use Ketoconazol ratiopharm

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Adolescents and Adults

Wash the infected scalp and your hair with the Ketoconazol ratiopharm shampoo. Normally one palmful of shampoo is enough for one washing occasion. Leave the shampoo on the treated area for 3-5 minutes before rinsing.

The number of treatments needed with Ketokonazol ratiopharm depends on the ailment being treated and on whether the shampoo is used as a treatment or as a preventive measure.

Scaling of the scalp (dandruff) and reddish-brown, scaling patches of the scalp (seborrheic dermatitis): Wash with Ketoconazol ratiopharm shampoo twice weekly during a period of 2-4 weeks. In order to prevent recurrence of the inflammation, Ketoconazol ratiopharm can be used once weekly or once every other week.

Use in Infants and Children

The use of Ketoconazol ratiopharm shampoo is not recommended in infants and children.

If you use more Ketoconazol ratiopharm than you should

The Ketoconazol ratiopharm shampoo may not be swallowed. Should this, however, happen, please contact a doctor.

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: may affect up to 1 in 100 people

- folliculitis
- increased lacrimation
- alopecia
- dry skin
- changes of the hair structure
- skin rashes
- burning sensation of the skin
- erythema, irritation, pruritus and/or reactions on the site of application

Rare: may affect up to 1 in 1,000 people

- hypersensitivity
- taste disturbances (dysgeusia)
- eye irritation
- acne
- contact dermatitis
- skin disorders and exfoliation
- hypersensitivity and/or pustules on the site of application

Not known: frequency cannot be estimated from the available data

- angioedema
- urticarial
- changes in the hair colour

If the shampoo causes side effects, please stop using it.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via www.ravimiamet.ee. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ketoconazol ratiopharm

Keep this medicine out of the sight and reach of children.

This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the bottle and box after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and further information

What Ketoconazol ratiopharm contains

- The active ingredient is ketoconazole. One millilitre of shampoo contains 20 mg of ketoconazole.
- The other ingredients are sodium laurilsulphate, disodium monolauril ether sulphosuccinate, macrogol 120-methyl glucose dioleate, imidurea, coconut fatty acid diethanolamide, anhydrous citric acid, hydrolysed collagen, azorubine (colouring agent E122), perfume (Chantisque essence; contains contains α -isomethylionone, benzyl alcohol, benzyl benzoate, benzyl

cinnamate, citral, citronellol, coumarin, eugenol, farnesol, geraniol, hexyl cinnamon, isoeugenol, linalol) and purified water.

What Ketoconazol ratiopharm looks like and contents of the pack

Viscous, pink liquid.

60, 100 and 120 ml shampoo in plastic bottles.

Not all pack sizes may be marketed.

Marketing authorisation holder and manufacturer

Marketing authorisation holder

ratiopharm GmbH
Graf-Arco Strasse 3
89079 Ulm
Germany

Manufacturer

Laboratories Feltor S.A.
Barcelona
Spain

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder

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