

Ketozol 2% w/w Dandruff Shampoo

Ketoconazole

Read all of this leaflet carefully before you start taking 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 or nurse 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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet

1. What Ketozol Dandruff Shampoo is and what it is used for
2. What you need to know before you use Ketozol Dandruff Shampoo
3. How to use Ketozol Dandruff Shampoo
4. Possible side effects
5. How to store Ketozol Dandruff Shampoo
6. Contents of the pack and other information

ROWEX[®]

1 What Ketozol Dandruff Shampoo is and what it is used for

Ketozol Dandruff Shampoo is a clear and reddish solution for shampooing.

Ketoconazole is used to treat **fungal infections** caused for example by yeast fungi, on **greasy, reddish, inflamed scalp** in adults and adolescents.

2 What you need to know before you use Ketozol Dandruff Shampoo

Do not use Ketozol Dandruff Shampoo

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

Warnings and precautions

Talk to your doctor or pharmacist before using Ketozol Dandruff Shampoo.

If cortisone ointments, such as betamethasone or hydrocortisone, are being used

- on the same area,
- for a long period and
- you decide to stop this treatment:

Reduce the cortisone therapy gradually over 2-3 weeks while also using Ketoconazole.

Other medicines and Ketozol Dandruff Shampoo

No interactions with other medicines are known.

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

Pregnancy and breast-feeding

There are no risks known for the use of ketoconazole shampoo in pregnancy or lactation.

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

Driving and using machines

Ketozol Dandruff Shampoo has no influence on the ability to drive or use machines.

Ketozol 2% w/w Dandruff Shampoo contains potassium sorbate.

Potassium sorbate may cause local skin reactions (e.g. contact dermatitis).

3 How to use Ketozol Dandruff Shampoo

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

The recommended dose is for:

Adults and adolescents:

Fungal infections in the scalp:

Wash the infected area with the shampoo and rinse after 3-5 minutes.

Treatment: Twice weekly for 2-4 weeks.

Preventive treatment: Once weekly or once every second week.

If Ketozol Dandruff Shampoo gets in your eyes

Gently bathe your eyes in cold water.

If you swallow Ketozol Dandruff Shampoo

If you swallow any shampoo, tell your doctor straight away.

If you forget to use Ketozol Dandruff Shampoo

- If you miss a treatment with Ketozol Dandruff Shampoo, you should use it as soon as you remember

Continued on the next page >>

- Do not use the shampoo twice to make up for a missed treatment.

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.

Stop using Ketozol Dandruff Shampoo and tell your doctor straight away if you notice or suspect any of the following. You may need urgent medical treatment.

Uncommon (may affect up to 1 in 100 people)

- Severe irritation or reddening of the skin where the shampoo has been used, or other signs of allergy during the first few days of treatment.

Rare (may affect up to 1 in 1,000 people)

- Allergic reaction, swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing.
- Peeling or blistering of the skin.

Tell your doctor or pharmacist if you notice or suspect any of the following side effects:

Uncommon (may affect up to 1 in 100 people)

- Infection of the hair roots
- Increase in production of tears
- Unusual hair loss or thinning
- Dry skin, rash, burning feeling
- Changes in how your hair feels.

Rare (may affect up to 1 in 1,000 people)

- Taste impairment
- Irritation of the eyes
- Acne
- Flaking skin.

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

- Hives (also known as nettle rash or urticaria)
- Hair colour changes.

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. You can also report side effects directly via HPRa Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Ketozol Dandruff Shampoo

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

Do not store above 25°C.

Do not use Ketozol Dandruff Shampoo after the expiry date which is stated on the packaging. 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 other information

What Ketoconazole shampoo contains

- The active substance is ketoconazole. 1 g of shampoo contains 20 mg ketoconazole (2%)
- The other ingredients are sodium lauryl ether sulphate, disodium monolauryl ether sulphosuccinate, macrogol 120 methyl glucose dioleate, macrogol 7 glyceryl cocoate, imidurea, lauryldimonium hydroxypropyl hydrolysed animal collagen (consisting of: water, lauryldimonium hydroxypropyl hydrolysed collagen, phenoxyethanol, potassium sorbate, sodium chloride), coconut fatty acid diethanolamide, sodium hydroxide, sodium chloride, Ponceau 4 R (E124), hydrochloric acid, concentrated, purified water.

What Ketozol Dandruff Shampoo looks like and contents of the pack

Ketozol Dandruff Shampoo is a clear, reddish solution.

Pack sizes: 60 ml and 120 ml.

Marketing Authorisation Holder

Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturer

NextPharma GmbH, Im Wirrigen 25, Waltrop, Germany.

This medicinal product is authorised in the Member States of the EEA under the following names

Denmark:	Ketoc
Ireland:	Ketozol 2% w/w Dandruff Shampoo
Netherlands:	Ketoconazole Sandoz Shampoo 20, shampoo 20 mg/g
United Kingdom:	Ketoconazole 20 mg/g Shampoo

This leaflet was last revised in 10/2016.

I.M. L/97a 10-16
50062155