

PATIENT INFORMATION LEAFLET

Ketopine 20mg/g Shampoo Ketoconazole

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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any 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 Ketoconazole Shampoo is and what it is used for
2. What you need to know before you use Ketoconazole Shampoo
3. How to use Ketoconazole Shampoo
4. Possible side effects
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1. What Ketoconazole Shampoo is and what it is used for

Ketoconazole Shampoo is a medicated shampoo used for the treatment and prevention of infections of the scalp and skin associated with the fungus *Pityrosporum* such as:

- Seborrhoeic dermatitis - a dry or greasy scaling of the scalp and other parts of the body.
- Dandruff (*Pityriasis capitis*).

2. What you need to know before you use Ketoconazole Shampoo

Do not use Ketoconazole Shampoo if you

- are allergic to ketoconazole or any of the other ingredients of this medicine (listed in Section 6).

Warning and precautions

Talk to your doctor or pharmacist before using Ketoconazole Shampoo. Take special care with Ketoconazole Shampoo if you

- get it in your eyes as it may irritate. If this happens, bathe them gently with cold water.
- have been using steroids such as betamethasone or hydrocortisone for a long period of time. You must gradually reduce the application of these over 2 to 3 weeks as you start to use Ketoconazole Shampoo. This will help to stop your condition from flaring up while you are using Ketoconazole Shampoo. If you have any questions about stopping your steroid treatment, speak to your doctor or pharmacist.

Other medicines and Ketoconazole Shampoo

Tell your doctor or pharmacist if you are taking, have recently taken or might take 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 but, usually, Ketoconazole Shampoo can be used during pregnancy and breast-feeding.

Driving and using machines

Use of Ketoconazole Shampoo has no effect on your ability to drive or to use machinery.

Ketoconazole Shampoo contains methyl benzoate and benzyl benzoate

Methyl benzoate and benzyl benzoate are mildly irritating to the skin, eyes and mucous membranes.

3. How to use Ketoconazole Shampoo

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

Ketoconazole Shampoo is for use on your skin only. Do not swallow it.

For adults including the elderly and adolescents:

- Wet hair and scalp thoroughly with water.
- Apply sufficient Shampoo (approximately 5 ml) to produce enough lather to wash the scalp and hair.
- Gently massage the lather over the entire scalp.
- Leave for 3-5 minutes, before rinsing off thoroughly.

Your usual shampoo can be used as necessary between treatments with Ketoconazole Shampoo.

Frequency of application:

- twice a week for 2-4 weeks to relieve the condition
- to prevent the recurrence of symptoms, use once every 1-2 weeks

If you or someone else swallows Ketoconazole Shampoo by mistake:

- tell your doctor or pharmacist immediately (accidental swallowing of small quantities is normally harmless).

If you forget to use Ketoconazole Shampoo

- do not worry if you miss an application of Ketoconazole Shampoo
- restart your treatment as soon as you remember

If you have any further questions on the use of this product, 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 Ketoconazole Shampoo and tell your doctor straight away if you notice or suspect any of the following. You may need urgent medical treatment.

- Allergic reaction, swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing. This can affect fewer than 1 in 1000 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. This can affect fewer than 1 in 100 people
- Peeling or blistering of the skin. This can affect fewer than 1 in 1000 people

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

Uncommon side effects (affects fewer than 1 in 100 people)

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

Rare side effects (affects fewer than 1 in 1000 people)

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

The following side effects have been reported, however the precise frequency cannot be identified and therefore how often they occur is classed as unknown

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

Reporting of side effects

If you get 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: IMB Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.imb.ie; e-mail: imbpharmacovigilance@imb.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ketoconazole Shampoo

Do not store above 25°C.

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

Store in the original container, and keep the cap tightly closed.

Do not use Ketoconazole after the expiry date which is stated on the label or carton. The expiry date refers to the last day of that month.

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

6. Contents of the pack and other information

Each 1 g of Ketoconazole Shampoo contains

- **Active ingredient:** 20 mg ketoconazole
- **Other ingredients:** sodium laureth sulfate paste 70%, disodium laureth sulfosuccinate liquid 40%, sodium chloride, citric acid monohydrate, benzyl alcohol, tetrasodium EDTA, quaternium-15, polyquaternium-7, dexpanthenol, laureth-2, sodium hydroxide, erythrosine (E127), perfume (containing methyl benzoate, benzyl benzoate and benzyl alcohol) and purified water. *See end of Section 2 for further information.*

What Ketoconazole looks like and contents of the pack

Ketoconazole is a clear pink viscous solution, available in 60 ml, 100 ml and 120 ml white high density polyethylene (HDPE) bottles.

Marketing Authorisation Holder and Manufacturer

Pinewood Laboratories Ltd., Ballymacarbry, Clonmel, Co. Tipperary, Ireland.
PA 281/125/001
Text Revised: March 2014.

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