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- BLEED AREA**
- INSERT PIPS FRONT AND BACK FOR BLANK SHEET DETECTION AT PRINT**

**PATIENT INFORMATION LEAFLET**  
**Ketoconazole 2% w/w Shampoo**  
**Ketoconazole 20mg/5ml**

**Read all of this leaflet carefully before you start using this medicine.**

- 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 of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

**In this leaflet:**

1. What Ketoconazole Shampoo is and what it is used for
2. Before you use Ketoconazole Shampoo
3. How to use Ketoconazole Shampoo
4. Possible side effects
5. How to store Ketoconazole Shampoo
6. Further information

**1. WHAT KETOCONAZOLE SHAMPOO IS AND WHAT IT IS USED FOR**

Ketoconazole 2% w/w 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*).
- Pityriasis versicolor - a condition causing white to brown patches to develop on parts of the body.

**2. BEFORE YOU USE KETOCONAZOLE SHAMPOO**

**Do not use Ketoconazole Shampoo if you**

- are hypersensitive (allergic) to ketoconazole or any of the other ingredients of Ketoconazole 2% Shampoo (see Section 6).

**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.

**Taking or using other medicines**

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

**Pregnancy and breast-feeding**

Ask your doctor or pharmacist for advice before taking any medicine in pregnancy 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.

**3. HOW TO USE KETOCONAZOLE SHAMPOO**

Always use Ketoconazole Shampoo exactly as your doctor or pharmacist has told you. You should 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 adolescents and adults (including the elderly):

- Wet hair and scalp thoroughly with water.
- Apply sufficient Ketoconazole Shampoo 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:

For dandruff (*Pityriasis capitis*) or dry/greasy scaling of the scalp (seborrhoeic dermatitis) use Ketoconazole Shampoo:

- twice a week for 2 - 4 weeks to relieve the condition
- once every 1-2 weeks to stop it returning

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For white to brown patches on the skin (*Pityriasis versicolor*) use Ketoconazole Shampoo:

- once daily for a maximum of 5 days to relieve the condition
- if your patches usually return after exposure to the sun, apply once a day for the 3 days BEFORE exposure to the sun to stop them returning.

**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, Ketoconazole Shampoo 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 in 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 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 the Yellow Card Scheme at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). 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 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. Unused medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

**6. FURTHER INFORMATION**

**Each 1g of Ketoconazole 2% w/w Shampoo contains**

- **Active Ingredient:** 20mg 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, purified water.

**What Ketoconazole Shampoo looks like and contents of the pack**

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

**Marketing Authorisation Holder and Manufacturer**

Pinewood Laboratories Ltd., Ballymacarbray, Clonmel, Co. Tipperary, Ireland. PL 04917/0039

Text Revised: 08/2015

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