



PATIENT INFORMATION LEAFLET

DANDRAZOL

Anti-Dandruff Shampoo

(Ketoconazole 20 mg/g)

READ ALL OF THIS LEAFLET CAREFULLY BECAUSE IT CONTAINS IMPORTANT INFORMATION FOR YOU.

This medicine is available without prescription. However, you still need to use Dandrazol Anti-Dandruff Shampoo carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist. Please see section 4.

In this leaflet:

1. What Dandrazol Anti-Dandruff Shampoo is and what it is used for.
2. What you need to know before you use Dandrazol Anti-Dandruff Shampoo.
3. How to use Dandrazol Anti-Dandruff Shampoo.
4. Possible side effects.
5. How to store Dandrazol Anti-Dandruff Shampoo.
6. Further information.

1. WHAT DANDRAZOL ANTI-DANDRUFF SHAMPOO IS AND WHAT IT IS USED FOR

Ketoconazole, the active ingredient in Dandrazol Anti-Dandruff Shampoo, is an antifungal which is used to treat dandruff. It also treats inflammation associated with dandruff, relieving itching and redness.

Everyone has a type of fungus (yeast) called *Malassezia* (used to be called *Pityrosporum*) on their skin. It is natural and normally harmless. However, people with dandruff appear to have more *Malassezia* than usual. Ketoconazole works by destroying *Malassezia* (and other fungi) and can be used to treat and prevent dandruff caused by yeasts. This product is for use in adults and adolescents over 12 years.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE DANDRAZOL ANTI-DANDRUFF SHAMPOO

Do not use Dandrazol Anti-Dandruff Shampoo if:

- you are allergic to the active ingredient (Ketoconazole) or any of the other ingredients listed in section 6 of the leaflet. If this applies to you, get advice from a doctor or pharmacist without using Dandrazol Anti-Dandruff Shampoo.

Children and adolescents

Dandrazol Anti-Dandruff Shampoo is not recommended for use in infants and children under 12 years.

Warnings and Precautions

Take special care with Dandrazol Anti-Dandruff Shampoo

This medicine contains 380 mg sodium laureth sulfate in 1 g. Sodium laureth sulfate may cause local skin reactions (such as stinging or burning sensation) or increase skin reactions caused by other products when applied on the same area. As with any other shampoo, take care not to get Dandrazol Anti-Dandruff Shampoo into your eyes. If any does get into your eyes, bathe them gently with water.

Taking other medicines

The medicine in your shampoo is not absorbed into the body and is not known to interfere with other medicines. However, please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription or herbal medicines.

If you have been regularly using a lotion or cream containing a steroid (such as betamethasone or hydrocortisone) to control your dandruff, make sure you tell your doctor or pharmacist. They may tell you to stop using it. However, it is important not to suddenly stop using it but gradually use it less over 2-3 weeks. This will stop your condition flaring up while the shampoo starts to work.

If you have any questions about stopping your steroid lotion or cream, please speak to your doctor or pharmacist.

Pregnancy and breast-feeding

Dandrazol Anti-Dandruff Shampoo can be used if you are pregnant or during breast feeding.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

Driving and using machines

Dandrazol Anti-Dandruff Shampoo is not expected to affect you being able to drive or use any tools or machines.

3. HOW TO USE DANDRAZOL ANTI-DANDRUFF SHAMPOO

Dandrazol Anti-Dandruff Shampoo is for use in adults and adolescents over 12 years. Dandrazol Anti-Dandruff Shampoo is used to treat dandruff and also to prevent dandruff from coming back again and is for external use only.

Instructions for use

- Shake the bottle well.
- Wet your hair thoroughly with water.
- Apply a small amount of Dandrazol Anti-Dandruff Shampoo to your scalp and massage into a lather.
- Leave it on for 3 to 5 minutes, then rinse thoroughly with water.

Treatment for dandruff: Use Dandrazol Anti-dandruff Shampoo twice weekly (every 3 or 4 days) for 2-4 weeks. If your condition has not cleared by this time, please speak to your doctor or pharmacist.

To prevent dandruff from coming back: Use Dandrazol Anti-Dandruff Shampoo once every 1-2 weeks.

Do not use Dandrazol Anti-Dandruff Shampoo more often than directed. You can use your usual shampoo if you need

to wash your hair between treatments. If you have very thick or long hair, you can wash with your usual shampoo and then use Dandrazol Anti-Dandruff Shampoo.

What if the shampoo is swallowed?

Dandrazol Anti-Dandruff Shampoo is for external use only and should not be taken by mouth.

Accidental swallowing is normally harmless but as with all externally used products contact your doctor, pharmacist or casualty (Accident & Emergency) department straight away for advice. Take this leaflet and the bottle with you so that the medicine can be identified.

If you forget to use Dandrazol Anti-Dandruff Shampoo

Do not worry if you forget to use Dandrazol Anti-Dandruff Shampoo. Continue with it as soon as you remember.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Dandrazol Anti-Dandruff Shampoo can cause side effects, although not everybody gets them. Most people who use Dandrazol Anti-Dandruff Shampoo do not have problems with it.

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

- Allergic reactions, including 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
- Application site reactions including itching, or tender skin
- 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 and inflammation of the hair root
- 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)

- Change in the way some things taste
- Irritation of the eyes
- Acne
- Flaking skin
- Skin inflammation (dermatitis)

The following side effects have been reported, however the precise frequency cannot be identified and therefore how often they occur is 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 or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. HOW TO STORE DANDRAZOL ANTI-DANDRUFF SHAMPOO

Keep this and all medicines in a safe place out of the reach and sight of children.

Keep Dandrazol Anti-Dandruff Shampoo in its original container. Do not store above 25°C.

Do not use Dandrazol Anti-Dandruff Shampoo after the expiry date which is stated on the bottle or carton. Expiry date refers to the last date of the month. Return any unused Dandrazol Anti-Dandruff Shampoo which you no longer need to your pharmacist who will dispose of it properly.

6. FURTHER INFORMATION

What Dandrazol Anti-Dandruff Shampoo contains

Each gram of Dandrazol Anti-Dandruff Shampoo contains 20 milligrams of Ketoconazole.

Dandrazol Anti-Dandruff Shampoo also contains inactive ingredients: sodium laureth sulfate, disodium laureth sulfosuccinate, PEG-120 methyl glucose dioleate, PEG-7 glyceryl cocoate, imidurea, lauryldimonium hydroxypropyl hydrolysed collagen, cocamide DEA, sodium hydroxide, sodium chloride, Erythrosine (E127), hydrochloric acid and purified water.

What Dandrazol Anti-Dandruff Shampoo looks like and contents of the pack

Dandrazol Anti-Dandruff Shampoo is a clear pink solution stored in a white plastic bottle.

It is available in bottles of 60 ml, 80 ml or 100 ml. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Transdermal Limited, Building 1410, Arlington Business Park, Theale, Reading, RG7 4SA, UK

Manufacturer

Apollo Pharma Limited, Lower Woodhill Rd, Bury BL8 1AR

For any information about this medicine, please contact the Marketing Authorisation Holder.

This leaflet was revised in February 2023.

Product Licence number: PL 14308/0006

LTF0819

