



PATIENT INFORMATION LEAFLET

DANDRAZOL 2% Shampoo

(Ketoconazole 20 mg/g)

READ ALL OF THIS LEAFLET CAREFULLY BEFORE YOU START USING THIS MEDICINE. 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 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 Shampoo is and what it is used for.
2. Before you use Dandrazol Shampoo.
3. How to use Dandrazol Shampoo.
4. Possible side effects.
5. How to store Dandrazol Shampoo.
6. Further information.

1. WHAT DANDRAZOL SHAMPOO IS AND WHAT IT IS USED FOR

Ketoconazole, the active ingredient in Dandrazol Shampoo is an antifungal medicine which is used to treat fungal infections of the skin.

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 and a greasy skin condition called seborrhoeic dermatitis appear to have more *Malassezia* than usual. *Malassezia* is also associated with Tinea versicolor (otherwise known as pityriasis versicolor), a condition which causes white to brown patches to develop on parts of the body.

Dandrazol Shampoo works by destroying *Malassezia* (and other fungi) and can be used to treat and prevent fungal infections on the scalp and body such as:

- Dandruff
- a dry or greasy scaling of the scalp and other parts of the body (seborrhoeic dermatitis)
- irregular white to brown patches which occur on the body and sometimes appear after being in the sun (tinea/pityriasis versicolor)

These conditions may be itchy.

This product is for use in adults and adolescents over 12 years.

2. BEFORE YOU USE DANDRAZOL SHAMPOO

Do not use Dandrazol Shampoo if:

- you are allergic to the active ingredient (Ketoconazole) or any of the other ingredients listed in section 6 of the leaflet.

Do not use this medicine if the above applies to you. If you are not sure, talk to your doctor or pharmacist before using Dandrazol Shampoo.

Take special care with Dandrazol Shampoo

As with any other shampoo, take care not to get Dandrazol Shampoo into your eyes. If any does get into your eyes, bathe them gently with water.

Children and adolescents

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

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

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.

3. HOW TO USE DANDRAZOL SHAMPOO

Dandrazol Shampoo is for use in adults and adolescents over 12 years. Always use Dandrazol Shampoo exactly as your doctor has told you. Dandrazol Shampoo is for external use only.

Instructions for use

- Shake the bottle well.
- Wash the hair or affected skin thoroughly with water.
- Apply a small amount of Dandrazol Shampoo to your scalp or skin. If used on the scalp massage into a lather.
- Leave it on for 3 to 5 minutes, then rinse thoroughly with water.

Treatment for dandruff or dry/greasy scaling of the skin: Use Dandrazol Shampoo twice weekly (every 3 or 4 days) for 2–4 weeks. To prevent it coming back, use Dandrazol Shampoo once every 1-2 weeks.

Treatment for white to brown patches of the skin: Use Dandrazol Shampoo on the affected skin areas once a day for no more than 5 days. These patches can become more apparent on exposure to the sun, Dandrazol Shampoo can be used to reduce this effect as a single 3-day course, applied immediately before exposure to sunshine.

Do not use Dandrazol 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 Shampoo.

What if the shampoo is swallowed?

Dandrazol 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 Shampoo

Do not worry if you forget to use Shampoo. Continue with it 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, Dandrazol Shampoo can cause side effects, although not everybody gets them. Most people who use Dandrazol Shampoo do not have problems with it.

Stop using Dandrazol 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
- 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 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 SHAMPOO

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

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

Do not use Dandrazol 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 Shampoo which you no longer need to your pharmacist who will dispose of it properly.

6. FURTHER INFORMATION

What Dandrazol Shampoo contains

Each gram of Dandrazol Shampoo contains 20 milligrams of Ketoconazole.

Dandrazol 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 Shampoo looks like and contents of the pack

Dandrazol Shampoo is clear pink solution stored in a white plastic bottle. It is available on prescription in bottles of 120 ml.

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.

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TransDermal

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