

# Nizoral® Dandruff 20mg/g Shampoo

ketoconazole

## 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 Nizoral 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 get serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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## 1. WHAT NIZORAL DANDRUFF SHAMPOO IS AND WHAT IT IS USED FOR

Nizoral Dandruff Shampoo is used to treat and prevent dandruff and dry or greasy scaling of the scalp (seborrhoeic dermatitis), which is a more severe kind of dandruff.

The shampoo contains ketoconazole, which is an antifungal that targets an increased number of yeasts on the skin called *Malassezia*. These yeasts occur naturally on everyone's skin; however, people with dandruff and seborrhoeic dermatitis seem to have more *Malassezia*. The shampoo also treats the inflammation associated with dandruff, relieving scalp redness and itching.

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

## 2. BEFORE YOU USE NIZORAL DANDRUFF SHAMPOO

This product is suitable for most adults and adolescents aged 12 years and over, but a few people should not use it. If you are in any doubt, talk to your doctor or pharmacist.

### Do not use this product...

- If you have ever had an allergic (hypersensitivity) reaction to any of the ingredients.

If this applies to you, **get advice from a doctor or pharmacist without using Nizoral Dandruff Shampoo.**

### Pregnancy and breast-feeding

- You can use Nizoral Dandruff Shampoo if you are pregnant, think you might be pregnant or are breast-feeding.

### Take special care with Nizoral Dandruff Shampoo

- As with most shampoos, if any gets into your eyes bathe them gently with water.

If you have been regularly using a lotion or cream, which contains a steroid (such as *betamethasone* or *hydrocortisone*) to control your dandruff or seborrhoeic dermatitis, gradually use it less over 2 – 3 weeks as you start to use Nizoral Dandruff Shampoo. This will stop your condition flaring up while Nizoral Dandruff Shampoo starts to work. If you have any questions about stopping your steroid lotion or cream, **speak to your doctor or pharmacist.**

### Driving and using machines

Using Nizoral Dandruff Shampoo will not affect your ability to drive or use machines.

## 3. HOW TO USE NIZORAL DANDRUFF SHAMPOO

Check the table below to see how much product to use.

- For external use only.
- Do not use more often than directed in the table. If you need to use a shampoo to wash your hair more often, use your usual shampoo. If your hair is very thick, you can wash with your usual shampoo and then use Nizoral Dandruff Shampoo.

### Adults and adolescents aged 12 years and over.

Age	How to apply
Adults and adolescents aged 12 years and over (for dandruff and dry/greasy scaling of the skin)	<ul style="list-style-type: none"><li>• Wet hair thoroughly</li><li>• Apply a small amount of Nizoral Dandruff Shampoo to your scalp and massage into a lather.</li><li>• Leave the lather on your scalp for 3-5 minutes</li><li>• Rinse thoroughly</li></ul>
<ul style="list-style-type: none"><li>• Use every 3 or 4 days for 2-4 weeks</li><li>• If your scalp has not cleared within 4 weeks, speak to your doctor or pharmacist.</li><li>• To keep your scalp clear and to prevent dandruff returning, use Nizoral Dandruff Shampoo once every 1-2 weeks. If you stop using Nizoral Dandruff Shampoo altogether, your symptoms may become a problem again.</li></ul>	

### If anyone accidentally swallows this product

If anyone accidentally swallows Nizoral Dandruff Shampoo, contact a doctor or your nearest Accident & Emergency department (Casualty) taking this leaflet and pack with you.

### If you forget an application

If you forget to use Nizoral Dandruff Shampoo use as per the directions next time you wash your hair.

## 4. POSSIBLE SIDE EFFECTS

Like all medicines, Nizoral Dandruff Shampoo can cause side effects, although not everybody gets them.

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

- 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 100 people

**Effects which may occur include:**

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

- Taste impairment
- Infection of the hair roots
- Irritation of the eyes and increase in production of tears
- Acne
- Unusual hair loss or thinning
- Skin rash and dry, flaking skin
- Inflammation of the skin
- Change in hair texture
- Skin burning sensation
- Problems at the site of application such as:
  - skin redness
  - skin irritation or blistering
  - hypersensitivity or reaction
  - itching

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
- swelling of the face, lips or throat

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 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 NIZORAL DANDRUFF SHAMPOO**

- Keep this medicine out of the sight and reach of children.
- Do not store above 25° C.
- Do not use this product after the expiry date shown on the packaging.

**6. FURTHER INFORMATION**

**What's in this product?**

**The active ingredient in 1 g of Nizoral dANDRUFF Shampoo is ketoconazole 20 mg**

**Other ingredients are:** sodium lauryl ether sulfate, disodium monolauryl ether sulphosuccinate, coconut fatty acid diethanolamide, laurdimonium hydrolysed animal collagen, macrogol 120 methyl glucose dioleate, sodium chloride, sodium hydroxide, imidurea, hydrochloric acid, erythrosine (E127) and purified water.

The product imported from Belgium also contains Perfume mix

**What the product looks like:** Nizoral Dandruff Shampoo is a pink liquid shampoo. It is available in bottles containing 60ml, 100ml or 120ml contained in an outer cardboard carton.

**Product procured within the EU, repackaged and distributed by the Parallel Product Authorisation**

**Holder:** PCO Manufacturing, Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath.

**Manufacturer**

Nizoral Shampoo is manufactured by Janssen Pharmaceutica NV, Turnhoutseweg 30, B-2340 Beerse, Belgium or McGregor Cory, Middleton Close, Banbury, OX 16 4RS, UK.

**Parallel Product Authorisation Number**

Nizoral 20mg/g Shampoo PPA 465/42/1

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