

Nizoral[®]

Anti-Dandruff Shampoo

ketoconazole

- This product is used to treat and prevent dandruff.
- The shampoo is for use by adults and adolescents over 12 years.
- **Do not use this product:**
 - If you have ever had a **bad reaction** to any of the ingredients. *For the list of ingredients see section 6* ▶
- **Follow the usage instructions carefully.** These are shown in the dosage table. *See section 3* ▶

Now read this whole leaflet carefully before you use this product. Keep the leaflet: you might need it again.

1 What the product is for

Nizoral Anti-Dandruff Shampoo is used to treat and prevent 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 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 over 12 years.

2 Before using this product

This product is suitable for most people, 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 a **bad reaction** to any of the ingredients.

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

⚠️ If you are pregnant or breast-feeding

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

⚠️ Special warnings about this product

- This medicine contains 24% w/w sodium laurilsulfate in each application. Sodium laurilsulfate 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 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, gradually use it less over 2 – 3 weeks as you start to use Nizoral Anti-Dandruff Shampoo. This will stop your condition flaring up while Nizoral Anti-Dandruff Shampoo starts to work. If you have any questions about stopping your steroid lotion or cream, **speak to your doctor or pharmacist.**

3 How to use this product

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 Anti-Dandruff Shampoo.

📄 Adults and adolescents over 12 years.

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

⚠️ If anyone accidentally swallows this product

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

STADA material number

turn over ▶

Pharma code

! If you forget an application

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

4 Possible side-effects

Nizoral Anti-Dandruff Shampoo can have side-effects like all medicines, although these don't affect everyone and are usually mild.

If you experience any of the following, stop using the medicine and talk to your doctor:

- Severe allergic reactions including swelling of the face, lips, tongue or throat

Uncommon side-effects (less than 1 in 100 people) which may occur include:

- Application site reactions including itching, irritation, blistering, red, dry or tender skin or a skin burning sensation
- Inflamed hair follicles, hair loss or changes in hair texture
- Increased tear production
- Skin rash and dry skin

Rare side-effects (less than 1 in 1000 people) which may occur include:

- A change in the way some things taste
- Eye irritation
- Acne
- Skin inflammation (dermatitis)
- Flaking skin
- Application site reactions including blistering and over-sensitivity (allergic) reactions
- General allergic reaction (over sensitivity)

Other side effects which occur but it is unknown how often:

- Hair discolouration and hives, which is known as nettle rash or urticaria

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

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

5 Storing this product

Keep 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. The expiry date refers to the last day of that month.

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

What's in this product?

The active ingredient in 1 g of Nizoral Anti-Dandruff Shampoo is 20 mg ketoconazole.

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, concentrated hydrochloric acid, imidurea, sodium hydroxide, erythrosine sodium (E127), purified water.

What the product looks like

Nizoral Anti-Dandruff Shampoo is a pink liquid shampoo. It is available in bottles of 60 ml.

Product Licence holder:

Thornton & Ross Ltd., Linthwaite, Huddersfield, HD7 5QH, UK.

Manufacturer:

Janssen Pharmaceutica NV, Turnhoutseweg 30, B-2340 Beerse, Belgium.

This leaflet was revised July 2020.

Nizoral is a registered trade mark.

