

PACKAGE LEAFLET: INFORMATION FOR THE USER

Nizoral® 20mg/g Shampoo (ketoconazole)

Read all of this leaflet carefully because it contains important information for you.

You need to use Nizoral 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 contact your doctor or pharmacist.

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

1. What Nizoral Shampoo is and what it is used for

Nizoral 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. It is also used to treat the irregular white to brown patches which occur on the body and sometimes appear after being in the sun (tinea/pityriasis versicolor).

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*. Tinea versicolor (otherwise known as pityriasis versicolor), a condition which causes white to brown patches to develop on parts of the body, is also associated with *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 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 Shampoo.**

Pregnancy and breast-feeding

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

Take special care with Nizoral 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 Shampoo. This will stop your condition flaring up while Nizoral Shampoo starts to work. If you have any questions about stopping your steroid lotion or cream, **speak to your doctor or pharmacist.**

Taking other medicine

There are no restrictions with the use of other medicines.

Using Nizoral Shampoo with food and drink.

Nizoral Shampoo can be used at the same time as taking food and drink.

3. How to use Nizoral 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 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)	▪ Wet hair thoroughly. ▪ Apply a small amount of Nizoral Shampoo to your scalp and massage into a lather. ▪ Leave the lather on your scalp for 3 – 5 minutes. ▪ Rinse thoroughly.

▪ 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 Shampoo once every 1 – 2 weeks. If you stop using Nizoral Shampoo altogether, your symptoms may become a problem again.
Adults and children (for white/brown patches on the skin):
For white/brown patches on the skin: Treat the affected areas with Nizoral shampoo once a day for up to 5 days. These patches can become more apparent on exposure to the sun. This effect can be reduced by a single 3-day course of Nizoral shampoo applied immediately before exposure to the sun.

If anyone accidentally swallows this product

If anyone accidentally swallows Nizoral 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 Shampoo use as per the directions next time you wash your hair.

4. Possible side-effects

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

Stop using Nizoral 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

If you experience any side-effects not included in this leaflet or are not sure about anything, **talk to your doctor or pharmacist.**

5. How to store Nizoral Shampoo

Keep the product out of the sight and reach of children.

Do not store above 25°C.

Do not use the shampoo after the expiry date (Exp) which is clearly marked on the bottle label and carton. This usually refers to the last day of that month.

If you have any Nizoral Shampoo left over which you no longer need, please return it to your pharmacist for safe disposal.

If this product appears to be discoloured, damaged or show any other signs of deterioration, please return to your pharmacist who will advise you further.

6. Further information

What's in this product?

The active ingredient in Nizoral Shampoo is ketoconazole. Each gram contains 20mg ketoconazole.

Like other shampoos, Nizoral Shampoo also contains other ingredients which clean your hair. The other ingredients are sodium lauryl ether sulphate, 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 sodium (E127) and purified water.

What the product looks like and contents of the pack

Nizoral Shampoo is a pink viscous shampoo.

It is available in bottles of 120 ml.

Manufacturer

Nizoral Shampoo is manufactured by: Janssen Pharmaceutica NV, Turnhoutseweg 30, 2340 Beerse, Belgium or McGregor Cory Ltd, Exel, Middleton Close, Banbury, Oxon, OX16 4RS, UK.

Procured from within the EU by the Parallel Product Authorisation holder: Imbat Ltd, Unit L2, North Ring Business Park, Santry, Dublin 9.

This product is repackaged by: Doncaster Pharmaceuticals Group Ltd, Kirk Sandall, Doncaster, South Yorkshire, DN3 1QR, UK.

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