

# Nizoral<sup>®</sup> Shampoo 2%

Ketoconazole (20mg/g)

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## What Nizoral Shampoo is used for

Nizoral Shampoo is used to treat and prevent skin infections caused by fungi or yeasts. Both skin and scalp can be treated with the shampoo.

## How Nizoral Shampoo works

Nizoral Shampoo rapidly relieves scaling and pruritis, which are usually associated with seborrheic dermatitis, pityriasis capitis (dandruff) and pityriasis versicolor.

## Before you use Nizoral Shampoo

### - When you must not use it

If you know you are hypersensitive (allergic) to the formulation of this product. Symptoms of hypersensitivity include itching and red skin, occurring after application.

### Pregnancy and lactation

There is no known risk with the use of Nizoral Shampoo in pregnancy or breast-feeding.

### - Before you start use it

Tell your healthcare professional (doctor or

pharmacist) if you have allergies to any other medicines, foods, preservatives or dyes.

### - Taking other medicines

If you are using Corticosteroids (cortisone-type medicines) in creams, ointment or lotion. If you are using such a medicine, check with your doctor or pharmacist before starting treatment with Nizoral Shampoo. You may start with Nizoral Shampoo right away, but do not stop using the corticosteroid from one day to the next. The skin might react by redness and itching.

It is recommended that the steroid therapy be gradually withdrawn over a period of 2 – 3 weeks, while using Nizoral Shampoo to prevent any potential rebound effect.

If in doubt, please consult your healthcare professional.

## How to use Nizoral Shampoo

### - How much to use

Wash the infected parts of the skin or scalp with Nizoral Shampoo and allow the product to soak in for 3 to 5 minutes before rinsing.

Make sure you thoroughly wash the skin or scalp itself and not just the hair.

Usually a palmful of shampoo suffice for one wash

### - When to use it

Use as directed by your doctor or pharmacist.

### - How long to use it

Scales on the scalp (dandruff) and reddish brown patches with yellow or white scaling in the face or on the chest (seborrheic dermatitis).

- For treatment, twice a

week for 2 to 4 weeks.

- To prevent relapse, once a week or once every 2 weeks.

Small brown or white-colored, irregular patches on the trunk (pityriasis versicolor).

- For treatment, once a day for 5 days.
- To prevent relapses: before exposure to sunlight, once a day for 3 consecutive days.

### - If you forget to use it

If you miss a treatment with Nizoral Shampoo, you should use it as soon as you remember. Do not use the shampoo twice to make up for a missed treatment.

### - If you use too much (overdose)

Nizoral Shampoo should not be swallowed. If Nizoral Shampoo is accidentally swallowed, contact your doctor, emergency department or national poison centre.

## While you are using it

### - Things you must do

Use Nizoral Shampoo as instructed by doctor or pharmacist.

### - Things you must not do

Use Nizoral Shampoo in infants and children below 12 years of age.

### - Things to be careful of

Avoid contact with the eyes. If this happens, however, rinse the eyes with cold water immediately.

## Side effects

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

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Application site reactions including collection of pus within the skin or hair follicles (pustules), shedding of skin, inflamed hair follicles, itching, irritation, skin burning sensation, red, dry or tender skin; rash; acne; hair loss or hair color or texture changes; and eye irritation or increased tearing may occur infrequently. Hypersensitivity (allergic) reactions; sudden swelling of the skin or mucous membranes usually of the face, eyes, or lips; hives; localized itchy skin rash (eczema); or distorted taste perception may also occur infrequently. In case you do not tolerate the shampoo, discontinue treatment.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [npra.gov.my](http://npra.gov.my) [Consumers→Reporting Side Effects to Medicine (ConSERF) or Vaccines (AEFI)].

## Storage and Disposal of Nizoral Shampoo

### - Storage

Always keep the bottle properly closed. Do not use Nizoral Shampoo after the date printed after "EXP", even if it has been stored properly.

Keep out of the reach and sight of children.

Store below 25°C.

### - Disposal

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.

## Product Description

### - What it looks like

Pink-orange liquid for topical application, containing the broad spectrum synthetic antifungal agent ketoconazole in a concentration of 2% in an aqueous suspension.

### - Ingredients

- Active ingredient(s)  
Ketoconazole

- Inactive ingredients Sodium lauryl ether sulphate, disodium monolauryl ether sulphosuccinate, coconut fatty acid diethanolamide, laurdimonium hydrolyzed animal collagen, macrogol 120 methyl glucose diolate, sodium chloride, hydrochloric acid, imidurea, perfume bouquet, sodium hydroxide, erythrosine sodium and purified water.

### - MAL number(s) :

MAL19900346ACRZ

## Manufacturer

OLIC (Thailand) Limited  
166 Bangpa-In Industrial Estate, Udomsorayuth Road, Moo 16, Bangkrason, Bangpa-In, Ayutthaya, 13160, Thailand.

## Product Registration Holder

Apex Pharmacy Marketing Sdn Bhd  
No. 2, Jalan SS13/5, 47500 Subang Jaya, Selangor, Malaysia.

## Date of revision

14 April 2023

## Serial Number

NPRA (R1/3) 26012023/024