

**ARTWORK PANEL**

3D Models  
For more information, please call Matt Barras on +44 01482 710380 or e-mail 3D@sonoco-trident.com

**Master Ref:** S1530919  
**Trident Reference No:** TR2571074  
**SKU Description:** Nizoral 2% 100ml Shampoo Allian-MY 457254 LFT

**Brand:** Alliance  
**Range:** Nizoral  
**Product:** Shampoo  
**Pack Type:** Leaflet  
**Pack Size:** 100ml  
**Action:** C  
**Date:** 07/07/23  
**Country:** Malaysia

**CAD Ref:** BEE-LFT-88.9x228.6mm  
**Manufacturing Site:** Olic  
**Printer:** Thai O.P.P Public company Limited  
**Substrate:** White Paper


**Barcode Type:** N/A  
**Magnification:** N/A  
**Pharmacode No/NE:** N/A

**Font Size (Main Body Copy):** 6.00pt

**Technical & Non Printing Items**  
■ Cutter ■ Guides

**Colours**  

Process Black	1
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 Connaught House, Connaught Road,  
 Kingswood Business Park, Hull, HU7 3AP, England.  
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**Sm•Art check results:** G=0; O=3; R=0; - CS - 07/07/23 12:26:05

228.6 mm

88.9 mm

MY1000025

# Nizoral®

## SHAMPOO 2%

### Ketoconazole 2%

**FOR TOPICAL USE ONLY**

**DESCRIPTION**  
 Nizoral® Shampoo 2% contains the synthetic broad spectrum antifungal agent, ketoconazole. One gram contains 20mg ketoconazole. The shampoo formulation consists of 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.

**PROPERTIES**

*Pharmacodynamics*  
 Pharmacotherapeutic group: Antifungal for Topical Use, Imidazole and triazole derivatives; ATC code: D01AC08

Ketoconazole, a synthetic imidazole dioxolane derivative with potent antifungal activity

Nizoral® Shampoo 2% rapidly relieves scaling and pruritus, which are usually associated with seborrhoeic dermatitis, pityriasis capitis (dandruff) and pityriasis versicolor.

*Pharmacokinetics*  
 Plasma concentrations of ketoconazole were not detectable after topical administration of Nizoral® Shampoo 2% on the scalp. Plasma levels were detected after topical administration of Nizoral® Shampoo 2% on the whole body.

**INDICATIONS**  
 Treatment and prophylaxis of infections in which the yeast *Malassezia* (previously called *Pityrosporum*) is involved, such as, seborrhoeic dermatitis and pityriasis capitis (dandruff). Treatment of pityriasis versicolor (localised)

**CONTRAINDICATIONS**  
 Nizoral® Shampoo 2% is contraindicated in individuals with a known hypersensitivity to any of its ingredients.

**WARNINGS & PRECAUTIONS**  
 In patients who have been on prolonged treatment with topical corticosteroids, it is recommended that the steroid therapy be gradually withdrawn over a period of 2 to 3 weeks, while using Nizoral® Shampoo 2% to prevent any potential rebound effect.

Avoid contact with the eyes. If the shampoo should get into the eyes, they should be bathed with cool water.

**PREGNANCY**  
 There are no adequate and well-controlled studies in pregnant women. Plasma concentrations of ketoconazole were not detectable after topical administration of Nizoral® Shampoo 2% to the scalp of non-pregnant humans. Plasma levels were detected after topical administration of Nizoral® Shampoo 2% on the whole body. There are no known risks associated with the use of Nizoral® Shampoo 2% in pregnancy.

**BREAST-FEEDING**  
 There are no adequate and well-controlled studies in lactating women. There are no known risks associated with the use of Nizoral Shampoo 2% in lactation.

**PAEDIATRIC USE**  
 The safe and effective use of Nizoral Shampoo 2% in infants and children under the age of 12 years has not been established

**DOSAGE AND ADMINISTRATION**  
 The infected areas of the skin or the scalp should be thoroughly washed with Nizoral® Shampoo 2%, which should be left on the skin/scalp for 3 to 5 minutes before rinsing.

**Dosage**  
 Usually, a painful of shampoo suffices for one wash.

**Treatment:**  
 - Pityriasis versicolor: once daily for 1 to 3 days.  
 - Seborrhoeic dermatitis and pityriasis capitis: twice weekly for 2 to 4 weeks.

**Prophylaxis:**  
 - Seborrhoeic dermatitis and pityriasis capitis: once every one or two weeks.

**ADVERSE REACTIONS**

*Clinical trial data*  
 The safety of Nizoral® Shampoo 2% was evaluated in 2890 subjects in 22 clinical trials where Nizoral® Shampoo 2% was administered topically to the scalp and/or skin.

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88.9 mm

228.6 mm

No adverse drug reactions (ADRs) were reported in  $\geq 1\%$  of Nizoral® Shampoo 2%-treated subjects.

Adverse drug reactions that occurred in  $< 1\%$  of Nizoral® Shampoo 2%-treated subjects in the clinical datasets are listed in Table 1.

**Table 1. Adverse Drug Reactions Reported in  $< 1\%$  of 2890 Nizoral® Shampoo 2%-treated Subjects in 22 Clinical Trials**

System Organ Class
Preferred Term
<b>Eye Disorders</b>
Eye irritation
Increased lacrimation
<b>General Disorders and Administration Site Conditions</b>
Application site erythema
Application site irritation
Application site hypersensitivity
Application site pruritus
Application site pustules
Application site reaction
<b>Immune System Disorders</b>
Hypersensitivity
<b>Infections and Infestations</b>
Folliculitis
<b>Nervous System Disorders</b>
Dysgeusia
<b>Skin and Subcutaneous Tissue Disorders</b>
Acne
Alopecia
Dermatitis contact
Dry skin
Hair texture abnormal
Rash
Skin burning sensation
Skin disorder
Skin exfoliation

#### Post-marketing experience

Adverse drug reactions first identified during post-marketing experience with Nizoral® Shampoo 2% are included in Table 2. In each table, the frequencies are provided according to the following convention:

Very common	$\geq 1/10$
Common	$\geq 1/100$ and $< 1/10$
Uncommon	$\geq 1/1,000$ and $< 1/100$
Rare	$\geq 1/10,000$ and $< 1/1,000$
Very rare	$< 1/10,000$ , including isolated reports.

In Table 2, ADRs are presented by frequency category based on spontaneous reporting rates.

**Table 2. Adverse Drug Reactions Identified During Post-marketing Experience with Nizoral® Shampoo 2% by Frequency Category Estimated from Spontaneous Reporting Rates**

#### Skin and Subcutaneous Tissue Disorders

Very Rare Angioedema, Urticaria, Hair color changes

#### OVERDOSAGE

In the event of accidental ingestion, supportive and symptomatic measures should be carried out. To avoid aspiration, neither emesis nor gastric lavage should be performed.

#### HOW SUPPLIED

Plastic containers with 100ml.

#### STORAGE CONDITIONS

Store below 25°C

#### SHELF LIFE

24 months

#### Keep out of reach of children

#### Jauhi dari kanak-kanak

#### MANUFACTURED BY:

OLIC (Thailand) Limited  
166 Bangpa-In Industrial Estate, Udomsorasayuth 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

TR2571074

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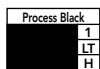
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