

Nizoral Shampoo

NAME OF THE MEDICINAL PRODUCT

NIZORAL® shampoo 2%

QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains 20 mg ketoconazole.
For excipients, see List of Excipients.

PHARMACEUTICAL FORM

Shampoo for topical application to the scalp and skin.

CLINICAL PARTICULARS

Therapeutic Indications

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

Posology and Method of Administration

The affected areas of the skin or the scalp should be washed with NIZORAL® shampoo, which should be left on the skin/scalp for 3 to 5 minutes before rinsing.

Treatment:

- Pityriasis versicolor: once daily for 5 days.
- Seborrhoeic dermatitis and pityriasis capitis: twice weekly for 2 to 4 weeks.

Prophylaxis:

- Pityriasis versicolor: once daily for 3 days during a single treatment course before the summer.
- Seborrhoeic dermatitis and pityriasis capitis: once every 1 or 2 weeks.

Contraindications

Known hypersensitivity to ketoconazole or any of the excipients.

Special Warnings and Special Precautions for Use

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have been on prolonged treatment with topical corticosteroids, it is recommended that the steroid therapy be gradually withdrawn over a period of 2 to 3 weeks, while using NIZORAL® shampoo, to prevent any potential rebound effect.

Increased hair shedding is often associated with seborrhoeic dermatitis and dandruff, and has been rarely reported with the use of NIZORAL® shampoo.

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

Interactions with Other Medicinal Products and Other Forms of Interaction

None known.

Pregnancy and Lactation

There are no adequate and well-controlled studies in pregnant or lactating women. There are no known risks associated with the use of NIZORAL® shampoo in pregnancy or lactation.

Effects on Ability to Drive and Use Machines

None since ketoconazole is not absorbed percutaneously.

Undesirable Effects

As with other shampoos, a local burning sensation, itching or contact dermatitis (due to irritation or allergy) may occur on exposed areas. Oily and dry hair have been reported rarely with the use of NIZORAL® shampoo.

In rare instances, mainly in patients with chemically damaged hair or grey hair, a discoloration of the hair has been observed with the use of NIZORAL® shampoo.

Additional adverse drug reactions reported in postmarketing reports with NIZORAL® shampoo are included in Table 1. The frequencies are based on spontaneous reporting rates, according to the following convention:

Very common	≥1/10
Common	≥1/100 and < 1/10
Uncommon	≥1/1000 and <1/100
Rare	≥1/10000, <1/1000
Very rare	<1/10000, including isolated reports

Table 1. Adverse Drug Reactions Identified During Postmarketing Experience with NIZORAL® shampoo by Frequency Category Estimated from Spontaneous Reporting Rates

Immune System Disorders

Very rare Hypersensitivity

Skin and Subcutaneous Tissue Disorder

Very rare Alopecia (Also see Special Warnings and Special Precautions For Use), Rash, Urticaria, Skin irritation, Dry skin

General Disorders and Administration Site Conditions

Very rare Application site reaction

Overdose

Not expected as NIZORAL® shampoo is intended for external use only.

In the event of accidental ingestion, only supportive measures should be carried out. To avoid aspiration, emesis or gastric lavage should not be performed.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic Properties

Ketoconazole, a synthetic imidazole dioxolane derivative, has a potent antifungal activity against dermatophytes, such as *Trichophyton* spp., *Epidermophyton* spp., *Microsporum* spp., and yeasts, such as *Candida* spp. and *Malassezia* spp. (*Pityrosporum* spp.). NIZORAL® shampoo rapidly relieves scaling and pruritus, which are usually associated with seborrhoeic dermatitis, pityriasis capitis (dandruff) and pityriasis versicolor.

Pharmacokinetic Properties

Plasma concentrations of ketoconazole were not detectable after topical administration of NIZORAL® shampoo on the scalp. Plasma levels were detected after topical administration of NIZORAL® shampoo on the whole body.

Preclinical Safety Data

Preclinical data reveal no special hazard for humans based on conventional studies including acute oral and dermal toxicity, primary ocular irritation, repeat-dose dermal irritation and dermal toxicity.

PHARMACEUTICAL PARTICULARS

List of Excipients

Sodium laureth sulphate, disodium monolaurate sulphosuccinate, coconut fatty acid diethanolamide, laurdimonium hydrolyzed animal collagen, macrogol 120 methyl glucose dioleate, perfume bouquet, imidurea, hydrochloric acid, sodium hydroxide, erythrosine sodium, sodium chloride and purified water.

Incompatibilities

None known.

Shelf Life

Observe expiry date on the outer pack.

Special Precautions for Storage

Store between 15 and 25°C.

Keep out of reach of children.

Nature and Contents of Container

60 and 100 ml white high density polyethylene (HDPE) bottles with polypropylene (PP) cap, and 6 ml polyester/Alu/PE sachets.

Instructions for Use and Handling

The infected parts of the skin should be washed with NIZORAL® shampoo, allowing the product to soak in for 3 to 5 minutes before rinsing. The skin itself should be thoroughly washed, not just the hair.

Usually, a palmful or 1 sachet of shampoo suffices for one wash.

DATE OF REVISION OF THE TEXT

March 2008



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