

# Ketoconazole<sup>®</sup> Shampoo

Ketoconazole USP 2%

## Description

Ketoconazole, a synthetic imidazole dioxolane derivative, has a potent antifungal activity against dermatophytes, such as *Trichophyton sp.*, *Epidermophyton sp.*, *Microsporum sp.*, and yeasts, such as *Candida sp.* and *Malassezia sp.* (*Pityrosporum sp.*).

Ketoconazole 2% shampoo rapidly relieves scaling and pruritus, which is usually associated with Seborrhoeic Dermatitis, Pityriasis Capitis (dandruff) and Pityriasis versicolor.

## Composition

**Ketoconazole<sup>®</sup> 100 ml Shampoo:** Each ml shampoo contains Ketoconazole USP 20 mg.

## Indications

Treatment and prophylaxis of infections in which the yeast *Malassezia* (previously called *Pityrosporum*) is involved, such as-

- Dandruff (Pityriasis capitis)
- Pityriasis versicolor (localized)
- Inflammatory skin condition with greasy, red and scaly areas (Seborrhoeic dermatitis)

## Dosage & administration

**Seborrhoeic dermatitis and Dandruff:** Two times in a week for 2 to 4 weeks.

**Pityriasis versicolor:** Once daily for 5 days.

## Prophylaxis

**Seborrhoeic dermatitis and Pityriasis capitis (Dandruff):** Once every 1 or 2 weeks.

**Pityriasis versicolor:** Once daily for 3 days during a single treatment course before the summer.

## Method of administration

To use the Ketoconazole 2% (**Ketoconazole<sup>®</sup> Shampoo**), follow these steps:

- Use a small amount of water to wet the area where Ketoconazole 2% shampoo is to be applied
- Apply the shampoo to the affected skin/scalp and a large area around it
- Use fingers to rub the shampoo until it forms lather
- Leave the shampoo on skin/scalp for 5 minutes
- Rinse the shampoo off skin/scalp with water

## Contraindication

Known hypersensitivity to Ketoconazole or any of the excipients.

## Side effects

Topical treatment with Ketoconazole 2% shampoo is generally well tolerated. As with other shampoos, a local burning sensation, itching, or contact dermatitis (due to irritation or allergy), may occur on exposed areas. In rare instances, mainly in patients with chemically damaged hair or gray hair, a discoloration of the hair has been observed with the use of Ketoconazole 2% shampoo.

## Use in pregnancy and lactation

Since Ketoconazole is not absorbed through the skin after topical application, Ketoconazole 2% shampoo is not contraindicated in pregnancy and lactation.

## 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 Ketoconazole 2% shampoo to prevent any potential rebound effect. Avoid contact with the eyes. If the shampoo enters the eyes, rinse immediately with plenty of water.

## Drug Interactions

Not Known.

## Over dosage

Not expected as Ketoconazole 2% shampoo is intended for external use only. Accidental oral ingestion is usually followed by nausea and vomiting due to detergent, only supportive measures should be carried out. Store in a cool (Below 25° C temperature) and dry place protected from light.

## Storage

Keep this medication in the container it came in, tightly closed, and out of reach of the children. Store it at room temperature and do not allow it to freeze. Protect the medication from light and keep away from excess heat and moisture.

## Packaging

**Ketoconazole<sup>®</sup> 100 ml Shampoo:** Each carton contains a plastic bottle containing 100 ml shampoo.



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