

Description:

Ketoconazole is a broad spectrum synthetic antifungal agent which inhibits the growth of dermatophytes, such as *Trichophyton sp. Epidermophyton sp. Microsporum sp.* and yeasts, such as *Candida sp.* and *Malassezia sp. (Pityrosporum sp.)*.

Composition:

Each ml shampoo contains Ketoconazole USP 20 mg.

Indications:

Ketozol shampoo is indicated in the treatment of

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

Dosage and application:

To use Ketozol shampoo, follow these steps:

- Shake the bottle well before each use.
- Apply the shampoo on wet hair & leave for 5 minutes after forming lather.
- Rinse the hair thoroughly with water.
- Use twice a week.

Treatment:

- Dandruff (Pityriasis capitis) and Seborrhoeic dermatitis- Twice a week.
- Pityriasis versicolor-Once daily for maximum 5 days.

Side Effects

Topical treatment with Ketoconazole 2% shampoo is generally well tolerated. As with other shampoos, a local burning sensation, itching or contact dermatits (due to irritation or allergy) may occur on exposed areas. Oily and dry hair may occur rarely.

Precautions:

In patients who have been on prolonged treatment with topical corticosteroids, it is recommended that the steroid therapy should be gradually withdrawn over a period of 2 to 3 weeks, while using Ketoconazole 2% shampoo to prevent any potential rebound effect.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 into the eyes, rinse immediately with plenty of water.

Contraindications:

It is contraindicated for known hypersensitivity to Ketoconazole or any of the excipients.

Use in pregnancy & lactation:

Ketoconazole is not detected in plasma after chronic shampooing that's way Ketoconazole 2% shampoo is not contraindicated in pregnancy and lactation.

Use in children:

Safety and efficacy have not been established.

Drug Interactions:

Not known.

Overdose:

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.

Storage:

- Store below 30° C, protect from light.
- Keep away from children.

Packing

Ketozol Shampoo: Plastic bottle containing 60 ml/100 ml shampoo.

