

Ketoconazole 2%

Presentation

Dancel®Shampoo: Each gram shampoo contains Ketoconazole BP 20 mg.

Description

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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* spp.(*Pityrosporum* spp). Ketoconazole 2% shampoo rapidly relieves scaling and pruritus, which are usually associated with Seborrhoeic dermatitis, Pityriasis capitis (dandruff) and Pityriasis versicolor.

Indications and Uses

Treatment and prophylaxis of infections in which the yeast *Malassezia* is involved, such as-

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

Dosage and Application

To use the Ketoconazole 2% shampoo, follow these steps:
• Shake the bottle well before use

- 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

Treatment

Seborrheic dermatitis and Dandruff: twice weekly for 2 to 4 weeks. Pityriasis versicolor: once daily for 5 days.

Prophylaxis

Seborrheic dermatitis and Dandruff: once every 1 or 2 weeks.

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

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.

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have been on prolonged treatment with topical corticosteroids, it is recommended that the steroid therapy be gradually withdrawn over a period of 2 to 3 weeks, while using Ketoconazole 2% shampoo to prevent any potential rebound effect.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

Use in Pregnancy and Lactation

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

Contraindications Known hypersensitivity to ketoconazole or any of the excipients.

Drug Interactions

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.

- 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.

Commercial Pack

Dancel Shampoo: Each plastic bottle contains 100 ml of shampoo.

