

**INSTRUCTION
For medical use**

DERMAZOLE®

Composition:

active substances: ketoconazole;

Each 1 ml of shampoo contains 20 mg of ketoconazole;

excipients: cocodiethanolamide, sodium lauryl ether sulfate, disodium monolauryl ether sulphasuccinate, macrogol 120 methyl glucose dioleate, propylene glycol, concentrated hydrochloric acid, sodium chloride, sodium hydroxide, butylhydroxytoluene (E 321), imidurea, Ponceau 4R (E 124), fragrance CK D00923, water purified.

Pharmaceutical form. Shampoo.

Main physical and chemical properties: transparent, pink viscous liquid with pleasant odour.

Pharmacotherapeutic group.

Antifungals for topical use. Imidazole and triazole derivatives.

ATC Code D01A C08.

Pharmacological properties.

Pharmacodynamics.

Ketoconazole, a synthetic imidazole dioxolane derivative, has a potent antimycotic and fungistatic activity against dermatophytes such as *Trichophyton sp.*, *Epidermophyton sp.*, *Microsporum sp.*, and against yeasts, such as *Candida sp.* and *Malassezia furfur* (*Pityrosporum ovale*). Ketoconazole shampoo relieves itching and squamation, usually occurring in case of dandruff, seborrhoeic dermatitis and tinea (pityriasis) versicolor.

Pharmacokinetics.

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

Clinical characteristics.

Indications.

Prevention and treatment of skin and hair infections in which the yeast *Malassezia* (previously called *Pityrosporum*) is likely to be involved, such as dandruff, seborrhoeic dermatitis and tinea (pityriasis) versicolor.

Contraindications.

Dermazole® shampoo is contra-indicated in patients with a known hypersensitivity to any of its ingredients.

Interaction with other medicinal products and other forms of interactions.

None known.

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have been on prolonged treatment with topical corticosteroids, it is recommended that the steroid therapy be gradually withdrawn over a period of 2 to 3 weeks, while using Dermazole[®] shampoo, to prevent any potential rebound effect.

Keep out of the eyes. If the shampoo should get into the eyes, they should be bathed with water.

Dermazole[®] shampoo contains buthylhydroxytoluene (E 321), it can cause topical skin reactions (e.g. dermatitis contact) or eyes and mucosa irritation.

Dermazole[®] shampoo contains propylene glycol, which may cause skin irritations.

Use in pregnancy and lactation.

There are no adequate and well-controlled studies in pregnant or lactating women. Plasma concentrations of ketoconazole were not detectable after topical administration of ketoconazole shampoo to the scalp of non-pregnant women. Plasma levels were detected after topical administration of ketoconazole shampoo on the whole body. There are no known risks associated with the use of ketoconazole shampoo in pregnancy or lactation.

Influence on velocity reactions in driving motor transport or operating other machines.

Dermazole[®] shampoo has no influence on the ability to drive and use machines.

Administration and dosage.

Wash affected areas with Dermazole[®] shampoo and leave for 3–5 minutes before rinsing.

Treatment:

- dandruff and seborrhoeic dermatitis (seborrhoeic eczema): twice weekly for 2–4 weeks;
- tinea versicolor: once daily for 5 days.

Prophylaxis:

- dandruff and seborrhoeic dermatitis (seborrhoeic eczema): once every 1–2 weeks;
- tinea versicolor: once daily for 3 days (single treatment course) before exposure to sunshine.

Children.

Safety and effectiveness of using Dermazole[®] shampoo by children aged before 12 have not been determined.

Overdose.

Since the shampoo is for external use only, overdose symptoms are unlikely to develop.

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

Adverse reactions.

Immune system disorders: hypersensitivity, including angioedema and urticaria.

Skin and subcutaneous tissue disorders: alopecia, dry skin, hair texture abnormal, rash, skin burning sensation, acne, dermatitis contact, skin disorder, skin exfoliation, increased greasiness or dryness of hair, hair colour changes (in patients with chemically damaged or grey hair).

Eye disorders: increased lacrimation, eye irritation.

Nervous system disorders: dysgeusia (distortion of the sense of taste).

Infections and infestations: folliculitis.

General disorders and administration site conditions: erythema, irritation, itching, feeling of discomfort, hypersensitivity, pustules at the site of application.

Shelf-life.

4 years.

Storage conditions.

Store at a temperature not more than 25°C in the original package.

Keep out of reach of children.

Package.

Shampoo 8 ml in a sachet. There are 20 sachets in a carton box.

Shampoo 50 ml or 100 ml are in a bottle, neck bottles covered with shrink wrapped cap. There is 1 flacon in a carton box.

Conditions of supply.

Without prescription.

Manufacturer.

KUSUM HEALTHCARE PVT LTD.

Address.

SP-289 (A), RIICO Industrial area, Chopanki, Bhiwadi, Dist. Alwar (Rajasthan), India.

Last revision date.