APPROVED
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Registration certificate
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INSTRUCTION
For medical use

DERMAZOLE®

Composition:
active substances: ketoconazole;
Each 1 g of cream contains 20 mg of ketoconazole;
excipients: propylene glycol, cetostearyl alcohol, cetomacrogol 1000, white soft paraffin, mineral oil light, disodium edetate, sodium sulfite anhydrous (E 221), polysorbate 80, purified water.

Pharmaceutical form. Cream.
Main physical and chemical properties: homogenous white cream.

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 activity against dermatophytes such as *Trichophyton spp.*, *Epidermophyton floccosum* and *Microsporum spp.*, and against yeasts, including *Malassezia spp.* and *Candida spp.* The effect on *Malassezia spp.* is particularly pronounced.
Ketoconazole inhibits ergosterole biosynthesis in fungi and changes composition of other lipid components in membrane.
Ketoconazole cream acts rapidly on pruritus, which is commonly seen in dermatophyte and yeast infections, associated with the presence of *Malassezia spp*. This symptomatic improvement is observed before the first signs of healing are observed.
Pharmacokinetics.
Plasma concentrations of ketoconazole were not detectable after topical administration of Dermazole® cream in adults on the skin.

Clinical characteristics.
Indications.
For topical application in the treatment of dermatophyte infections of the skin such as Tinea corporis, Tinea cruris, Tinea pedis and Tinea manus infections due to *Trichophyton rubrum*, *Trichophyton mentagrophytes*, *Microsporum canis* and *Epidermophyton floccosum*, and also for the treatment of cutaneous candidosis and Tinea (pityriasis) versicolor.
Dermazole® cream should be also indicated in the treatment of seborrhoeic dermatitis, a skin condition related to the presence of *Malassezia furfur*.

Contraindications.
Dermazole® cream is contra-indicated in patients with a known hypersensitivity to any of the ingredients or to ketoconazole itself.

Interaction with other medicinal products and other forms of interactions.
None known.

Special precautions.
Dermazole® cream is not for ophthalmic use.
If coadministered with a topical corticosteroid, to prevent a rebound effect after stopping a prolonged treatment with topical corticosteroids it is recommended to continue applying a mild topical corticosteroid in the morning and to apply Dermazole® cream in the evening, and to subsequently and gradually withdraw the topical corticosteroid therapy over a period of 2–3 weeks.
Dermazole® cream contains propylene glycol which may cause skin irritations.
Dermazole® cream contains cetyl alcohol which may cause skin irritations (e.g. contact dermatitis).

Use in pregnancy and lactation.
There are no adequate and well-controlled studies in pregnant or lactating women. Plasma concentrations of ketoconazole are not detectable after topical administration of Dermazole® cream to the skin of non-pregnant women. There are no known risks associated with the use of Dermazole® cream in pregnancy or lactation.

Influence on velocity reactions in driving motor transport or operating other machines.
Dermazole® cream has no influence on the ability to drive and use machines.

Administration and dosage.
Dermazole® cream is for cutaneous administration. Cream should be applied to the affected and surrounding areas. General measures with regard to hygiene should be observed to control sources of infection or re-infection.
For all patients the duration of treatment should be based on the individual response for the therapy.

Indications	Frequency of application	Duration of treatment	Notes
Cutaneous candidosis (yeast infections)	Once daily	2–3 weeks	The treatment should be continued until a few days after the disappearance of all signs and symptoms. The diagnosis should be reconsidered if no clinical improvement is noted after 4 weeks.
Tinea (pityriasis) versicolor	Once daily	2–3 weeks	
Tinea manus	Once daily	2–4 weeks	
Tinea corporis	Once daily	3–4 weeks	
Tinea cruris	Once daily	4–6 weeks	
Tinea pedis	Once daily	4–6 weeks	
Seborrhoeic dermatitis (*usual therapy*)	Once-twice daily *	2–4 weeks	
Seborrhoeic dermatitis (*maintenance therapy*)	Once or twice a week		

* Depending on the severity of the infection.

Children.
There are no data on the use of Dermazole® cream in paediatric patients.

Overdose.
Topical Application.
Excessive topical application may lead to erythema, oedema and a skin burning sensation, which will disappear upon discontinuation of the treatment.
Ingestion.
In the event of accidental ingestion, supportive and symptomatic measures should be carried out.

Adverse reactions.
Immune system disorders: hypersensitivity reactions;
General disorders and administration site conditions: erythema, itching, bleeding, discomfort, dryness, inflammation, irritation, paresthesia, site reactions.
Skin and subcutaneous tissue disorders: burning sensation, rash, bullous eruption, dermatitis contact, skin exfoliation or sticky skin, urticaria.

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.
15 g or 30 g in a tube in a carton package.

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.