Dermofix *cream*

Sertaconazole 2%

Pharmacological action

Sertaconazole is a new topical antimycotic endowed with a potent fungicidal activity, with a broad activity spectrum where the pathogenic yeasts (Candida albicans, C. tropicalis, C. spp. Pityrosporum orbiculare), dermatophytes (Trichophyton, Epidermophyton and Microsporum) and other causing and accompanying agents in skin and mucous membranes infections like the gram-positive germs (Staphylococcus and Streptococcus) are included.

Composition

Per g of cream:
Sertaconazole nitrate.. ..... 20 mg
Excipients (ethyleneglycol and polyethyleneglycol palmito stearate, lauroyl macroglycerides, glyceryl isostearate, light paraffin oil, nipagin, sorbic acid, water) q.s.

Indications

Topical treatment of surface skin mycoses, such as dermatophytosis, Tinea pedis (athlete's foot), Tinea cruris (Hebra's eczema), Tinea corporis (herpes circinatus), Tinea barbae (beard mycosis) and Tinea manus, Candidiasis (Moniliasis) and Pityriasis versicolor (Pityrosporum orbiculare, Malassezia furfur formerly).

Dosage

Apply the cream one or two times every day (preferably at night or in the morningand at night), mildly and uniformly on the lesion, trying, besides, to embrace 1 cm of sound skin (approximately) around the affected area.
The duration of the treatment to obtain the healing, varies from one patient to another, in function of the etiologic agent and location of the infection. In general, four weeks of treatment are recommended to ensure a complete clinical and microbiological healing and the non appearance of relapses, though, in many cases, this clinical-microbiological healing appears earlier, between two and four weeks of treatment should be applied.

Contraindications
Do not administer it in case of known allergy to the product or to one of the constituents of the excipient.

Precautions
DERMOFIX should not be used for ophthalmological treatments.

Drugs interactions
No interactions have been reported.

Undesirable effects
Its safety in local treatment is excellent; no toxic or photosensitizing effects have been observed. There have been isolated reports of slight local and transient erythematous reaction during the first treatment days; treatment discontinuance has not been required.

Use during pregnancy
After the topical application of big amounts, no plasma levels will be detected; in spite of this, its innocuousness in pregnant women has not been demonstrated; therefore the risk-benefit ratio should be evaluated before its use during pregnancy and in nursing mothers.

Overdosage and treatment
Considering the active substance concentration and the administration route, intoxication is impossible; however, in case of accidental ingestion, the appropriate symptomatic treatment should be applied.

How supplied
2% Cream.
Packages containing 20 g and 30 g.

Keep a temperature lower than 30°C.
Drugs should be kept out of the reach and sight of children.