

SUMMARY OF PRODUCT CHARACTERISTICS

Name of the medicinal product: Dermofix® Cream.2% Sertaconazole.

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 q.s. **Indications:** Tropical treatment of surface skin mycoses, such as dermatophytosis, *Tinea pedis* (athlete's foot), *Tinea cruris* (Hebra's eczema), *Tinea corporis* (herpes circinatus), *Tineabarbae* (beard mycosis) and *Tinea manus*, Candidiasis (Moniliasis) and Pityriasis versicolor (*Pityrosporum orbiculare*, *Malassezia furfur* for merly). **Dosage:** Apply the cream one or two times every day (preferably at night or in the morning and 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. **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 20g and 30g.

Not all dosage forms are available.