

# Dermofix®

Sertaconazole 2 %

TOPICAL ROUTE

**Composition**  
Sertaconazole nitrate 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*, *Epidermo-phyton* and *Microsporum*) and other causing and accompanying agents in skin and mucous membranes infections like the gram-positive germs (*Staphylococcus* and *Streptococcus*) are included.

**Indications**  
Topical treatment of surface skin mycosis, 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 and administration**  
Apply the suitable form of **Dermofix®** 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.

**Dermofix® is present in 3 different forms for convenient use**

- **Dermofix® Cream** is suitable for localized, accessible skin areas with superficial mycotic (fungal) infections.
- **Dermofix® Solution** is particularly suitable for the skin zones which are difficult to access, especially those with wide areas of mycotic (fungal) infections.

The metered nebulizer, ensures uniform distribution of the active ingredients on the affected and the surrounding skin zones.

- **Dermofix® Powder** is especially indicated in the treatment of exudative mycotic (fungal) infections of the poorly aerated intertriginous skin areas (eg. inter-digital and sub-mammary). The special applicator, permits uniform application of the powder to the affected skin and the surrounding area. The duration of treatment to obtain the healing, varies from one patient to another, in function of the etiologic agent and location of infection. In general, four weeks of treatment are recommended to ensure a complete clinical and micro-biological 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 Imidazole derivatives.

**Precautions**  
**Dermofix®** should not be used for ophthalmological treatments.

**Drug 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 discontinuation 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 or 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**

- **Dermofix® Cream** 2%; aluminum tubes, each of 15 gm
- **Dermofix® Solution** 2%; plastic spray bottles, each of 15 ml
- **Dermofix® Powder** 2%; plastic bottles, each of 15 gm

Drugs should be kept out of the reach of children  
Do not store above 30°C.

#### THIS IS A MEDICAMENT

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep all medicines out of the reach of children.



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