

ZALAIN®

Sertaconazole 2%

Pharmacological action

Sertaconazole is a new topical antimycotic endowed with a potent fungicide 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

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 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 microbiologic 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

Are not known.

Precautions

ZALAIN 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 .

5g and 20g

Drugs should be kept out of the reach of children.