ZALAÍN® cream

(Sertaconazole nitrate 2%)

ANTI-FUNGAL

PRESCRIPTION DRUG ONLY

INTERNATIONAL NON-PROPRIETARY NAME
Sertaconazole nitrate

PRODUCT DESCRIPTION

Description: White-coloured semi-solid 2% cream of fluid consistency, odourless or with a faint fatty odour.

THERAPEUTIC PROPERTIES
Sertaconazole is an antifungal drug showing a broad spectrum of in vitro and in vivo activity against yeasts (Candida, Torulopsis, Trichosporum, Malassezia, Rhodotorua, Cryptococcus), dermatophytes (Mycrosposrum, Tricophyton and Epidermophyton) and opportunistic filamentous fungi (Aspergillus, Alternaria, Acremonium, Fusarium and Scopularopsis). Under suitable assay conditions, the minimum inhibitory concentration (MIC) ranges from 0.01-2 µg/ml for dermatophytes to 0.03-2 µg/ml for yeasts.
Besides the antifungal action, sertaconazole also acts against Gram-positive microorganisms (Streptococcus and Staphylococcus) and Gram-negative microorganisms (Bacteroides, Gardnerella vaginalis) inhibiting their growth to MICs that range from 4 to 32 µg/ml. It also shows trichomonacidal activity against Trichomonas vaginalis at concentrations from 50 to 100 µg/ml.

PHARMACODYNAMIC EFFECTS
Sertaconazole is an antifungal drug belonging to the imidazole class.
Sertaconazole inhibits the growth of pathogenic fungi causing a blockage at the level of ergosterol synthesis that produces the structural and functional change of the fungal cytoplasmic membrane. In addition, the exposure to sertaconazole causes a direct damage on the fungal plasma membrane which implies a fungicidal effect.

PHARMACOKINETIC PROPERTIES
Sertaconazole percutaneous absorption is negligible as plasmatic levels are not detectable even after chronic administration. Therefore, systemic effects are not foreseen.

CLINICAL USE
The efficacy of sertaconazole cream 2% was evaluated in 30 patients with Tinea pedis with a scheme of treatment of one application daily for 4 weeks (Bonifaz et al., 2011). Efficacy was evaluated as mycological cure which was obtained in 93.33% of the cases and treatment failures were in hyperkeratotic cases which require longer treatments.
100 patients with an established diagnosis of cutaneous dermatophytosis were analysed in a double-blind clinical trial comparative of sertaconazole 2% cream vs. miconazole 2% cream applied twice daily for 4 weeks (Ghaninejad et al., 2009). The results of this study indicate superiority of sertaconazole 2% cream in producing an early response in the patients treated for four weeks for cutaneous dermatophytosis. The same comparison was undertaken in a phase IV study with 260 patients suffering from cutaneous dermatophytosis from Tinea corporis or Tinea cruris (Sharma et al., 2011). Clinical cure was achieved in (62.3%) patients from the sertaconazole group and in only 57 patients receiving miconazole.
Patients enrolled in the study of Tamil Selvan et al. were divided into five groups of 30 patients that received amorolfine, sertaconazole, luliconazole, eberconazole, terbinafine (% are not disclosed). The test product needed to be applied once daily for 1 week in patients with Tinea cruris/ Tinea corporis and for 2 weeks in patients with Tinea pedis. (Tamil Selvan et al., 2013). Sertaconazole, under the conditions of this trial, showed higher efficacy followed by luliconazole, amorolfine, terbinafine and eberconazole.

A Phase III study designed as an open-label, multicentre study, was conducted in 29 children and adolescents aged between 2 and 16 years to evaluate the therapeutic efficacy in the treatment of cutaneous dermatophyte infections in paediatric population (Van Esso et al., 1995). A clinical cure was achieved in 75% of the patients after completing the 2-week treatment, and at 4 weeks, a clinical cure was documented in all children. Moreover, no special considerations regarding the age of the patients seem to be required for the use of sertaconazole 2% cream in paediatric populations.
From the data collected in clinical trials, it may be concluded that Sertaconazole 2% shows a favourable local and systemic safety profile even after repeated application of very high doses.

INDICATION
Topical treatment of epidermal dermatophytoses (tinea corporis, tinea cruris, tinea manus, tinea barbae and tinea pedis), cutaneous candidiasis, pityriasis versicolor.

RECOMMENDED DOSAGE
Apply Zalaín® 2% cream to the affected areas once or twice a day (preferably in the evening or morning and evening) also covering the adjacent area.
The usual duration of treatment is 3 to 4 weeks.
If there is no clinical recovery after 4 weeks of treatment, the diagnosis should be confirmed. Apply general hygienic measures to control infection and reinfection sources.
The posology for children older than 12 years is the same as that recommended for adults.

ROUTE OF ADMINISTRATION
Topical application.

CONTRAINDICATIONS
Do not give to individuals with known hypersensitivity to sertaconazole or to any of the excipients.

WARNINGS AND PRECAUTIONS
Do not use Zalaín® 2% cream for ophthalmic treatments. Avoid contact with eyes. In case of accidental contact, rinse the eyes with water.
In patients that have been treated for a long period with a topical corticosteroid and in order to avoid a possible appearance of sensitisation induced by corticosteroids, it is recommended to discontinue the treatment two weeks before the use of Zalaín® 2% cream.
Warnings for excipients
Zalaín® 2% cream contains sorbic acid as excipient and may cause local skin reactions (as contact dermatitis).
It also contains methyl p-hidroxybenzoate which may cause allergic reactions (possibly delayed).

DRUG INTERACTIONS
No interactions have been reported.

USE IN PREGNANCY AND LACTATION
Animal studies have revealed no teratogenic effect; hence there is no reason to expect such an effect in humans. However, there are no relevant clinical data on its innocuousness for newborn and pregnant women. Consequently, considering the administration route (topical application) and the lack of systemic passage, sertaconazole should only be used during pregnancy if necessary.
There are no data on the passage of sertaconazole into brest milk. Breastfeeding is not contraindicated but avoid the application to the nipple area.

UNDESIRABLE EFFECTS
Following the topical application of Zalaín® cream, skin disorders as erythema, burning sensation and itching may very rarely appear (<0.01%, that is, isolated cases). After the application of Zalaín® 2% cream, allergic reactions may possibly appear with the manifestation of itching, erythema or vesicles in the application area or in a scattered way.

OVERDOSAGE
As the use is only topical, overdose is not foreseen.
In case of accidental swallowing, apply suitable symptomatic therapy. In order to avoid inhalation, do not induce vomiting or perform a gastric lavage.

PRESENTATION
Aluminium-blind mouth collapsible tube inwardly coated with an epoxi-phenolic lacquer and a latex sealing band. White cap made from polyethylene.
Content of 20g of cream.

SHELF LIFE
3 years

STORAGE
Store below 30°C.
Keep out of reach of children!

Manufactured By
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Date of last revision

MALXXXXXXXXX

Malaysia – November 2020