SUMMARY OF PRODUCT CHARACTERISTICS

1. TRADE NAME OF THE MEDICINAL PRODUCT

DERMOFIX (Sertaconazole) 2% cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition per 100 g:

Sertaconazole nitrate (INN) 2.00 g

Excipients: Methyl p-hidroxybenzoate (E218), Sorbic acid (E200) and other excipients.

For complete list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

2% cream

4. CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

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

4.2 POSOLOGY AND METHOD OF ADMINISTRATION

Apply Dermofix 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 than that recommended for adults.

4.3 CONTRAINDICATIONS

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

4.4 SPECIAL WARNINGS AND SPECIAL PRECAUTION FOR USE

Do not use DERMOFIX 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 Dermofix 2% cream.

Warnings for excipients

Dermofix 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).

4.5 INTERACTION WITH OTHER MEDICAMENTS AND OTHER FORMS OF INTERACTION

No interactions have been reported.

4.6 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.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

No effects on the ability to drive and use machines are foreseen as, following the topical application, sertaconazol is not absorbed through the skin.

4.8 UNDESIRABLE EFFECTS

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

4.9 OVERDOSE

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.

5. PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Pharmacotherapeutic group: Dermatological antifungal for topical use.

Imidazole and triazole derivatives, ATC code D01AC14

Sertaconazole is an antifungal drug belonging to the imidazole class.

Mechanism of action:

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.

Pharmacodynamic effects.

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.

During the clinical development of sertaconazole cream, comparative clinical studies against placebo and against other topical antifungal as miconazole, bifonazole and sulconazole were carried out with more than 2000 patients suffering from skin dermatophytosis and candidiasis. In all the cases, sertaconazole showed an efficacy significantly higher than that of placebo. The degree of clinical healing achieved with sertaconazole after a 3-4-week treatment with 1-2 daily applications ranged between 46% and 90.6% of the patients. With regard to the mycological healing data achieved within the same period, it ranged from 82% to 98.3%. In all the cases, relapses were less frequent after the treatment with sertaconazole than with the other topical antifungal used.

5.2 PHARMACOKINETIC PROPERTIES

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

5.3 PRECLINICAL SAFETY DATA

The toxicological investigation of sertaconazole has been carried out by the study of the following aspects: Acute toxicity, subacute and chronic toxicity, toxicity on reproduction, genetic toxicity, local tolerance and phototoxicity. The results obtained allowed to conclude that sertaconazole is a highly safe antifungal. This is confirmed by quantifiable data such as the highest dose with no toxic effects and the safety margin supplied by the dose of 50 mg/kg in chronic studies and that of 100 mg/kg in reproduction studies.

6. PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Ethyleneglycol and polyethyleneglycol palmito stearate
Polyoxyethylenated and glycolyzed saturated glycerides C_{10}-C_{18}
Glycerol mono and di-isostearate
Light liquid paraffin (paraffin oil)
Methyl p-hydroxybenzoate (methylparaben) (E-218)
Sorbic acid (E-200)
Purified water

6.2 INCOMPATIBILITIES

Not reported

6.3 SHELF LIFE

3 years

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store in a dry place at temperature below 30 ºC

6.5 NATURE AND CONTENTS OF CONTAINER

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

Content of 30 g/60 g of cream.

6.6 INSTRUCTIONS FOR USE/HANDLING

No special requirements. See section 4.2