SUMMARY OF PRODUCT CHARACTERISTICS

(SmPC)

1. NAME OF THE MEDICINALPRODUCT

Fungusol® Cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Miconazole nitrate 2% w/w

(Each gram of cream contains 20mg of miconazole nitrate)

{For a full list of excipients, see section 6.1}

3. PHARMACEUTICAL FORM

Cream.
White homogeneous cream

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

- For the treatment of mycolic infections of the skin and nails. These include *Tinea pedis,*(athlete's foot),*Tinea corporis* caused by *Trichophyton rubrum*,*Trichophyton mentagrophytes* and *Epidermophyton floccosum;cutaneous candidiasis(moniliasis) Tinea versicolor* .
- Ringworm
- Onychomycosis
- Vaginal candidiasis.

4.2 Posology and method of administration

Fungal infections of the skin: Apply some cream to the lesions two times daily. Rub the cream into the skin with your finger until it has fully penetrated. If the powder is used with the cream, a once daily application of both formulations is recommended. The duration of therapy varies from 2 to 6 weeks depending on the localization and the severity of the lesion. Treatment should be continue at least one week after disappearance of all signs and symptoms.

Method of administration
Fungusol cream is administered externally (Cutaneous use).

4.3 Contraindications

Fungusol cream is contraindicated in individuals with a known hypersensitivity to miconazole/miconazole nitrate,other imidazole derivatives or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Severe hypersensivity reactions, including anaphylaxis and angioedema, have been reported during treatment with fungusol cream and and with other miconazole topical formulations. If a reaction suggesting hypersensitivity or irriation should occur, the treatment should be discontinued.Fungusol lotion must not come in

contact with the mucosa of the eyes.

4.5Interaction with other medicinal products and other forms of interaction

Miconazole administered systemically is known to inhibit CYP3A4/2C9. Due to the limited systemic availability after cutaneous application,clinically relevant interactions are unlikely to occur. However, in patients on oral anticoagulants, such as warfarin, caution should be exercised and anticoagulant effect should be monitored. The effects and side effects of some other drugs (e.g. oral hypoglycaemics and phenytoin), when co-administered with miconazole, can be increased and caution should be exercised.

4.6 Pregnancy and Lactation

Pregnancy

In animals miconazole nitrate has shown no teratogenic effects but is foetotoxic at high oral doses. Only small amounts of miconazole nitrate are absorbed following topical administration. However, as with other imidazole, miconazole nitrate should be used with caution during pregnancy.

Lactation

Topically applied miconazole is minimally absorbed into the systemic circulation, and it is not known whether miconazole is excreted in human breast milk. Caution should be exercised when using topically applied miconazole products during lactation

4.7 Effects on ability to drive and use machines

Not applicable

4.8 Undesirable effects

Local sensitivity reactions, skin burning sensation and itching.

4.9 Overdose

Symptoms

Cutaneous use: Excessive use can result in skin irritation, which usually disappears after discontinuation of the therapy**.**

Accidental ingestion: Stomach irritation may occur

Treatment

If accidental ingestion of fungusol cream, the stomach should be emptied by gastric lavage.

5. PHARMACOLOGICALPROPERTIES

5.1 Pharmacodynamics properties

Mechanism of action: Miconazole Nitrate is an imidazole antifungal agent and may act by interfering with the permeability of the fungal cell membrane. It has a wide antifungal spectrum and possesses some antibacterial activity.

5.2 Pharmacokinetic properties

Absorption: There is little absorption through skin or mucous membranes when miconazole nitrate is applied topically.

Distribution: Absorbed miconazole is bound to plasma protein (08.2%) and red blood cells (10.6%)

Metabolism and Excretion: The small amount of miconazole that isabsorbed is eliminated predominantly in feaces as both unchanged drug and metabolites.

5.3 Preclinical safety data

None stated

6. PHARMACEUTICALPARTICULARS

6.1 List of excipients

Parachlorometacresol
Liquid paraffin
Anhydrous lanolin
Propylene glycol
Stearic acid
Triethanolamine
Lanette wax
Disodium EDTA
Sodium metabisulphite
Methyl paraben
Petroleum jelly
Lavender oil

6.2 Incompatibilities

None known

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store below 30°C

6.5 Nature and contents of container

White plastic tube containing 20gm of cream

6.6 Special precautions for disposal

No special requirements

7. APPLICANT/MANUFACTURER

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