Drugfield PHARMACEUTICALS LIMITED

SUMMARY OF PRODUCT CHARACTERISTICS

Mycoten® Solution (Clotrimazole 2%$^{W}/_{W}$)

1. NAME OF THE MEDICINALPRODUCT

Mycoten® (Clotrimazole 2%$^{W}/_{W}$) Solution

2. QUALITATIVE AND QUANTITATIVECOMPOSITION

Each ml contains Clotrimazole 2% $^{W}/_{W}$

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Liquid (Solution)

4. Clinical particulars

4.1 Therapeutic indications

Mycoten® Solution should be used to treat all fungal skin infections due to dermatophytes, yeasts, moulds and other fungi.

It is particularly suitable for use on hairy skin and in fungal infections of the outer ear (otitis externa) and middle ear (otomycoses).

Posology and method of administration

Posology

Important Dosage and Administration Instructions

Use exactly as directed on the label, or as prescribed by your doctor. Do not use in larger or smaller amounts or for longer than recommended.

Do not take by mouth. Clotrimazole topical is for use only on the skin.

Wash your hands before and after using clotrimazole topical, unless you are using it to treat a hand infection.

Clean and dry the affected area. Apply a small amount of the cream (usually twice daily) for 2 to 4 weeks.

Do not cover the treated skin area unless your doctor tells you to. Avoid using bandages or dressings that do not allow air circulation. A light cotton-gauze dressing may be used to protect clothing.

Use this medicine for the full prescribed length of time. Your symptoms may improve before the infection is completely cleared. Skipping doses may also increase your risk of further infection that is resistant to antifungal medicine.

Call your doctor if your symptoms get worse, or if your condition does not improve after 4 weeks of treatment.

Store at room temperature away from moisture and heat.

Initial Dosage

Mycoten® Solution should be thinly and evenly applied to the affected area 2 or 3 times a day and gently rubbed in. A few drops are enough to treat an area of about the size of the hand. To prevent relapse, treatment should be continued for at least two weeks after the disappearance of all signs of infection.

There is no separate dosage schedule for the elderly or the young.

Method of administration

Topical administration

4.2 Contraindications

Hypersensitivity to clotrimazole or macrogol 400.

4.3 Special warnings and precautions for use

This product contains cetostearyl alcohol, which may cause local skin reactions (e.g. contact dermatitis).

4.4 Interaction with other medicinal products and other forms of interaction

No drug interactions have been reported by the manufacturer. However, you should tell your doctor about all the medicines you take including prescription and non-prescription medicines, vitamins, and herbal supplements. Not all drug interactions are known or reported and new drug interactions are continually being reported.

4.5 Pregnancy and Lactation

Pregnancy

There is a limited amount of data from the use of clotrimazole in pregnant women. Animal studies with clotrimazole have shown reproductive toxicity at high oral doses . At the low systemic exposures of clotrimazole following topical treatment, harmful effects with respect to reproductive toxicity are not predicted.

Clotrimazole can be used during pregnancy, but only under the supervision of a physician or midwife.

Lactation

Available pharmacodynamic/toxicological data in animals have shown excretion of clotrimazole/metabolites in milk after intravenous administration . A risk to the suckling child cannot be excluded. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from clotrimazole therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.

Females and Males of Reproductive Potential

No human studies of the effects of clotrimazole on fertility have been performed; however, animal studies have not demonstrated any effects of the drug on fertility.

4.6 Effects on ability to drive and use machines

Clotrimazole has no or negligible influence on the ability to drive or use machines.

4.7 Undesirable effects

Like all medicines, Mycoten Solution can cause side effects, although not everybody gets them. As with all medicines, some people may be allergic to the solution. If you are allergic, a reaction will occur soon after you start using it. If you experience an allergic reaction, stop using Mycoten Solution and tell your doctor straight away or contact the Accident and Emergency Department of your nearest hospital. Signs of an allergic reaction may include:

•Rash.

•Swallowing or breathing problems.

•Swelling of your lips, face, throat or tongue

.•Weakness, feeling dizzy or faint

.•Nausea

After you apply the solution you might experience:

•Itching, rash, blisters, burning, discomfort, swelling, irritation, redness or peeling of skin

4.8 Overdose

No risk of acute intoxication is seen as it is unlikely to occur following a single dermal application of an overdose (application over a large area under conditions favourable to absorption) or inadvertent oral ingestion. There is no specific antidote.

However, in the event of accidental oral ingestion, routine measures such as gastric lavage should be performed only if clinical symptoms of overdose become apparent (e.g. dizziness, nausea or vomiting). Gastric lavage should be carried out only if the airway can be protected adequately.

5. PHARMACOLOGICALPROPERTIES

5.1 Pharmacodynamics properties

Pharmacotherapeutic group: Antifungals for topical use – imidazole and triazole derivatives

ATC Code: D01A C01

Mechanism of Action

Clotrimazole acts against fungi by inhibiting ergosterol synthesis. Inhibition of ergosterol synthesis leads to structural and functional impairment of the fungal cytoplasmic membrane.

Clotrimazole has a broad antimycotic spectrum of action in vitro and in vivo, which includes dermatophytes, yeasts, moulds, etc.

Under appropriate test conditions, the MIC values for these types of fungi are in the region of less than 0.062-8.0 µg/ml substrate. The mode of action of clotrimazole is primarily fungistatic or fungicidal depending on the concentration of clotrimazole at the site of infection. In vitro activity is limited to proliferating fungal elements; fungal spores are only slightly sensitive.

In addition to its antimycotic action, clotrimazole also acts on gram-positive microorganisms (Streptococci / Staphylococci / Gardnerella vaginalis), and gram-negative microorganisms (Bacteroides).

In vitro clotrimazole inhibits the multiplication of Corynebacteria and gram-positive cocci - with the exception of Enterococci - in concentrations of 0.5-10 µg/ml substrate.

Primarily resistant variants of sensitive fungal species are very rare; the development of secondary resistance by sensitive fungi has so far only been observed in very isolated cases under therapeutic conditions.

Pharmacodynamics

Clotrimazole is a broad-spectrum antifungal agent that inhibits the growth of pathogenic yeasts by changing the permeability of cell membranes. The action of clotrimazole is fungistatic at concentrations of drug up to 20 mcg/mL and may be fungicidal in vitro against Candida albicans and other species of the genus Candida at higher concentrations . Unfortunately, resistance to clotrimazole, which was rare in the past, is now common in various patient populations .

Clotrimazole is generally considered to be a fungistatic, and not a fungicidal drug, although this contrast is not absolute, as clotrimazole shows fungicidal properties at higher concentrations

5.2 Pharmacokinetic properties

Pharmacokinetic investigations after dermal application have shown that clotrimazole is minimally absorbed from the intact or inflamed skin into the human blood circulation. The resulting peak serum concentrations of clotrimazole were below the detection limit of 0.001 µg/ml, suggesting that clotrimazole applied topically is unlikely to lead to measurable systemic effects or side effects.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on studies of repeated dose toxicity, genotoxicity and carcinogenicity.

Clotrimazole was not teratogenic in reproductive toxicity studies in mice, rats and rabbits. In rats high oral doses were associated with maternal toxicity, embryotoxicity, reduced fetal weights and decreased pup survival.

In rats clotrimazole and/or its metabolites were secreted into milk at levels higher than in plasma by a factor of 10 to 20 at 4hrs after administration, followed by a decline to a factor of 0.4 by 24 hrs.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polyethylene Glycol

Propylene Glycol

Benzyl Alcohol

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 Months

6.4 Special precautions for storage

Store below 30°C in tight container protected from light and moisture.

6.5 Nature and contents of container and special equipment for use, administration or implantation

Mycoten® Clotrimazole Solution is presented in sagomated plastic container with Tampa proof plastic screw caps containing 25ml of solution. This is then packed in a chip board container

6.6 Special precautions for disposal and other handling

No special requirements.

5 APPLICANT/MANUFACTURER

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