

 **Dermosporin[®] 1% Solution**
(Clotrimazole Topical Solution USP)

COMPOSITION:

Each ml contains:
Clotrimazole USP ... 10mg w/v
[USP Specs.]

DESCRIPTION:

Clotrimazole is a broad spectrum antimycotic with fungicidal action for skin infections and ear infection.

CLINICAL PHARMACOLOGY

MECHANISM OF ACTION:

Clotrimazole exerts its effect by altering the fungal cell membrane. Clotrimazole inhibits ergosterol synthesis by interacting with 14-alpha demethylase, a cytochrome P-450 enzyme that is necessary for converting lanosterol to ergosterol, an essential component of the membrane. Inhibition of ergosterol synthesis results in increased cellular permeability, causing leakage of cellular contents such as phosphorous-containing compounds and potassium. Clotrimazole does not appear to have the same activity upon human cholesterol synthesis. As a treatment for infectious diarrhea, Clotrimazole is thought to interfere with chloride and resulting fluid accumulation in epithelial cells lining the intestine.

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 mcg/ml, suggesting that Clotrimazole applied topically is unlikely to lead to measurable systemic effects or side effects.

INDICATIONS:

Clotrimazole is effective against all fungal skin infections due to dermatophytes (e.g. Trichophyton Species) yeast (e.g. Candida Species) moulds and other fungi. These include ringworm (tinea) infections, athlete's foot, paronychia pityriasis, versicolor, erythrasma, intertrigo, fungal nappy rash, Candida vulvitis and Candida balanitis. It is particularly suitable for use on hairy skin and in fungal infections of the outer ear (otitis externa) and middle ear (ostomycosis).

CONTRA-INDICATIONS:

Hypersensitivity to Clotrimazole or macrogol 400.

DOSAGE AND ADMINISTRATION:

Dermosporin 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. For ear infections, put 2-3 drops of Dermosporin Solution in the ear two or three times daily. 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.

OVERDOSAGE:

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 favorable to absorption) or inadvertent oral ingestion. There is no specific antidote.

Rev. 05-19/4

However, in the event of accidental oral ingestion, routine measures such as gastric lavage should be carried out only if the airway can be protected adequately.

PRECAUTIONS:

If irritation or sensitivity develops with the use of Clotrimazole, treatment should be discontinued and appropriate therapy instituted.

FERTILITY, PREGNANCY AND LACTATION:

Pregnancy:

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

Lactation:

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.

ADVERSE REACTIONS:

The following adverse reactions have been reported in connection with the use of Clotrimazole: erythema, stinging, blistering, peeling, edema, pruritus, urticaria, burning, and general irritation of the skin.

INTERACTION WITH OTHER DRUGS:

Heat reaction have been reported when Dermosporin Solution is used concomitantly with drops containing Gramicidin, Framycetin sulfate, and Dexamethasone sodium metasulfobenzoate in the ear.

INSTRUCTIONS:

For external use only.

Store below 30°C.

Protect from heat & light.

Keep out of reach of children.

PRESENTATION:

Dermosporin Solution is available in pack sizes of 20ml and 60ml.

ڈرمواسپورن® 1% محلول
(کلوٹرائمزول)

ہدایات:

صرف بیرونی استعمال کے لئے

۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔

گرمی اور روشنی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔



Manufactured by:
NABIQASIM INDUSTRIES (PVT) LTD.
17/24, Korangi Industrial Area,
Karachi-Pakistan.

Rev: 05-19/4