

PRODUCT LITERATURE

CANDINIL LOTION 1% W/V

Each 100 ml contains

Active Ingredient

Clotrimazole BP 1% w/v

Preservative:

Methyl Paraben BP 0.1%w/v

Contains Alcohol DN

Description

Odourless clear, colourless lotion

Pharmacodynamic Properties

Clotrimazole is an imidazole derivative with a broad spectrum of antimycotic activity. It also exhibits activity against *Trichomonas*, staphylococci, streptococci and *Bacteroides*. It has no effect on lactobacilli.

Mechanism of action:

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

Pharmacodynamic effects:

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

The mode of action of clotrimazole is 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.

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.

Pharmacokinetic Properties

Pharmacokinetics 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.

Indication

For the treatment of fungal infections caused by organism sensitive to clotrimazole.

Recommended Dosage

Apply a thin layer over the affected area 2-3 times a day.

Route of Administration

Topical

Contraindications

Known hypersensitivity to any of the components

Warnings and Precautions

Carcinogenicity

Studies in rats given oral doses of clotrimazole for 18 months have not shown that clotrimazole is carcinogenic.

Mutagenicity

Studies in Chinese hamsters given clotrimazole in five oral doses of 100 mg per kg of body weight (mg/kg) prior to testing have shown no mutagenic effects in the spermatophore chromosomes.

Pediatrics

Appropriate studies performed to date have not demonstrated pediatrics-specific problems that would limit the usefulness of topical clotrimazole in children.

Geriatrics

Appropriate studies on the relationship of age to the effects of topical clotrimazole have not been performed in the geriatric population. However, no geriatrics-specific problems have been documented to date

Interactions with Other Medicaments

Clotrimazole Cream may cause damage to latex contraceptives.

Consequently patients should be advised to use alternative precautions for at least five days after using this product.

Pregnancy and Lactation:

Pregnancy

Data on a large number of exposed pregnancies indicate no adverse effects of Clotrimazole on pregnancy or on the health of the fetus/newborn child. To date, no other relevant epidemiological data are available.

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

Side Effects / Adverse Reactions

As the listed undesirable effects are based on spontaneous reports, assigning accurate frequency of occurrence for each is not possible.

Immune system disorders: allergic reaction (syncope, hypotension, dyspnoea, urticaria).

Skin and subcutaneous tissue disorders: blisters, discomfort/pain, oedema, irritation, peeling/exfoliation, pruritus, rash, stinging/burning.

Overdose and Treatment

In the event of accidental oral ingestion, gastric lavage is rarely required and should be considered only if a life-threatening amount of clotrimazole has been ingested within the preceding hour or if clinical symptoms of overdose become apparent (e.g. dizziness, nausea or vomiting). It should be carried out only if the airway can be protected adequately.

Storage

Store below 30°C in a dry place, protected from direct light.
Keep away from reach of children.

Shelf Life

Expiry date: 2 years from date of manufacture

FOR EXTERNAL USE ONLY

Packing

Packed in plastic container of 10 ml, 20 ml and 250 ml

Name and Address of Registration Holder/ Distributor:

ZONTRON PHARMACEUTICALS SDN. BHD.

(445695-T)

Lot 10 & 11, PERDA Industrial Park,

Lorong IKS Simpang Ampat B,

14100 Simpang Ampat, S.P.S.,

Pulau Pinang, Malaysia.

Name and Address of Product Manufacturer:

TERAPUTICS SDN. BHD. (590500-W)

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