

PYP Antifungal Cream 1%w/w

Active Ingredient: Clotrimazole 1%w/w

Preservative: Chlorocresol 0.2%w/w

Product Description:

White colour, smooth application, sticky and phenolic odour cream.

Indication:

- All dermatomycoses due to dermatophytes (*Trichophyton* species) e.g. athlete's foot (tinea pedis), jock itch (tinea cruris) and ringworm (tinea corporis)
- All dermatomycoses due to yeast (*Candida* species) e.g. *candida vulvitis*, *candida balanitis*
- Dermatomycoses due to moulds and other fungi
- Skin diseases showing secondary infection with these fungi
- Pityriasis versicolor (tinea versicolor) due to *Malassezia furfur*

Recommended Dose:

General: The affected area should be washed and thoroughly dried. Thin layer of clotrimazole cream is evenly rubbed into the affected area twice daily. Treatment should continue for 2-4 weeks after the disappearance of all signs of infection to ensure mycological cure and prevent relapse.

Adult & Paediatric dosing based on type of infection:

- Candidiasis (topical): twice daily for up to 4 weeks
- Pityriasis versicolor (tinea versicolor): twice daily for up to 4 weeks
- Tinea corporis: twice daily for up to 4 weeks
- Tinea cruris: twice daily for up to 4 weeks
- Tinea pedis: twice daily for up to 4 weeks

Pharmacodynamics:

Clotrimazole is an imidazole derivative with a broad spectrum antimycotic activity.

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. Under appropriate test conditions, the minimum inhibitory concentration (MIC) values for these types

of fungi are in the region of less than 0.062-4(-8) mg/ml substrate. The mode of action of clotrimazole is primarily fungistatic. In-vitro activity is limited to proliferating fungal elements; fungal spores are slightly sensitive.

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

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

Primary 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.

Pharmacokinetics:

Absorption of clotrimazole is less than 0.5% after topical application.

Contraindication:

Hypersensitivity to the Clotrimazole or to any of the excipients.

Warning and Precaution:

For irritation or sensitivity caused with the use of clotrimazole; treatment should be discontinued and appropriate therapy instituted. The patient should be advised to use the medication for the full treatment time even though the symptoms may have improved. This medicine should be used in the first trimester of pregnancy after consideration of the benefit/risk relation and by physician decision. It is not known whether Clotrimazole is excreted in human being milk. As many drugs are excreted in human being milk, caution should be exercised with Clotrimazole used by nursing mothers.

Keep out of reach of children.

Jauhkan daripada capaian kanak-kanak.

Effects on Ability to Drive and Use Machines:

It is unlikely to impair a patient's ability to drive or use machinery.

Interactions with Other Medicaments: Not known

Pregnancy & Lactation:

Weigh the potential benefits of drug treatment against potential risks before prescribing this drug during pregnancy and breastfeeding.

Side Effect:

Local reactions include irritation, burning sensation, contact dermatitis, blister, edema, erythema, peeling of skin, pruritis, urticaria and stinging of skin.

Symptoms of Overdosage and Treatment:

Acute overdosage with topical application of clotrimazole is unlikely and would not be expected to lead to a life-threatening situation. In the case of overdose, there is no specific antidote.

Route of Administration:

Topical

Packing: 20g

Storage Condition:

Store below 30°C. Protect from light and moisture.

Shelf Life: 3 years

Product Registration Holder:

San Jiu Bio-Pharma Sdn Bhd
No. 7-1-6, Jalan Kampar Barat 9,
Taman Kampar Barat, 31900 Kampar, Perak.

Manufacturer:

Syarikat Wen Ken Drug Sdn Bhd
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Date of Revision: December 2023