

# PACKAGE INSERT TEMPLATE FOR CLOTRIMAZOLE CREAM / LOTION / SOLUTION/ DUSTING POWDER

## Brand or Product Name

*[Product name]* Cream/Lotion/Solution 1% w/w (w/v)

*[Product name]* Powder 1% w/w

## Name and Strength of Active Substance(s)

Clotrimazole 1% w/w (w/v)

## Product Description

*[Visual description of the appearance of the product (eg colour, odour, viscosity, texture etc)]*  
*eg White smooth cream*

*Clear, colourless lotion*

*Fine white to off-white powder with a pleasant odour*

## 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 only 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*).

*Updated Sept 2011*

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 and exerts a trichomonacidal action at 100 mg/ml.

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 application to skin/topical application

### **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

### **Recommended Dosage**

#### Cream/Lotion/Solution

*General:* The affected area should be washed and thoroughly dried. Thin layer of clotrimazole cream/lotion/solution 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: Cream/solution; twice daily for up to 4 weeks
- Tinea cruris(2 yr and older): Lotion; twice daily for 2 weeks
- Tinea pedis: twice daily for up to 4 weeks

Lotion is ideal for treatment of large lesions, hairy and intertriginous skin areas and for nails

*Updated Sept 2011*

### Powder

Clotrimazole powder may be used with the cream or solution and has been applied to prevent re-infection.

It should be dusted over the affected area several times daily as required

The powder may also be dusted inside articles of clothing and footwear which are in contact with the infected area.

### **Mode of Administration**

Topical

### **Contraindications**

Hypersensitivity to clotrimazole

### **Warnings and Precautions**

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

#### *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

### **Statement on Usage During Pregnancy and Lactation**

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

*Updated Sept 2011*

**Adverse Effects / Undesirable Effects**

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

**Overdose and Treatment**

Acute overdosage with topical application of clotrimazole is unlikely and would not be expected to lead to a life-threatening situation

**Storage Conditions**

*[eg Store below... °C]*

**Dosage Forms and Packaging Available**

*[Packaging type & pack size]*

Pack size: Liquid – max 250ml

Others – 60g

**Name and Address of Manufacturer**

*[Name & full address of manufacturer]*

**Name and Address of Marketing Authorization Holder**

*[Name & full address of marketing authorization holder]*

**Date of Revision of Package Insert**

*[day/month/year]*

*Updated Sept 2011*