

## **Summary of Product Characteristics:**

### **1. Name of the medicinal Product**

Clotrimazole Cream BP

### **2. Qualitative and Quantitative Composition**

#### **Qualitative declaration**

Clotrimazole BP

### **3. Pharmaceutical Form**

Clotrimazole BP.....1% w/w

Cream Base.....Q.S.

### **4. Clinical Particulars**

#### **4.1 Therapeutic Indications**

Clotrimazole 1% Cream is recommended for the treatment of All dermatomycoses due to moulds and other fungi (e.g. Trichophyton species).

All dermatomycoses due to yeasts (Candida species).

Skin diseases showing secondary infection with these fungi. Candidal nappy rash, vulvitis and balanitis.

#### **4.2 Posology and Method of Administration**

Adults:

The cream should be applied thinly 2-3 times daily and rubbed in gently. Treatment should be continued for at least one month for dermatophyte infections and at least two weeks for candida! infections.

Elderly: Refer to adult dosing.

#### **4.3 Contraindications**

Hypersensitivity to clotrimazole or any other ingredient in this medicine.

#### **4.4 Special Warnings and Special Precautions for Use**

Topical: When using topical formulation, avoid contact with eyes.

Pregnancy: There is a limited amount of data from the use of clotrimazole in pregnant women. Clotrimazole can be used during pregnancy, but only under the supervision of a physician or midwife.

Lactation: It is not known whether this drug is excreted in human milk, caution should be exercised when clotrimazole is used by a

nursing woman.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

No clinically significant interactions have been identified.

#### **4.6 Fertility, Pregnancy and Lactation**

**Pregnancy:** There is a limited amount of data from the use of clotrimazole in pregnant women. Clotrimazole can be used during pregnancy, but only under the supervision of a physician or midwife.

**Lactation:** It is not known whether this drug is excreted in human milk, caution should be exercised when clotrimazole is used by a nursing woman.

##### **Fertility:**

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.

#### **4.7 Effects on ability To Drive and use Machines**

Not Known

#### **4.8 Undesirable Effects**

Local reactions: irritation, redness and burning may occur.

Reporting of suspected adverse reactions: Healthcare professionals are asked to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) <https://pv.pharmacyboardkenya.org>

#### **4.9 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, 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). Gastric lavage should be carried out only if the

airway can be protected adequately.

## 5. Pharmacological Properties

### 5.1 Pharmacodynamic properties

**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.

### 5.2 Pharmacokinetic Properties

**Absorption:** Clotrimazole is minimally absorbed from the intact or inflamed skin into the human blood circulation.

**Time to peak, serum:** Vaginal cream: approximately 24 hours.

**Excretion:** Clotrimazole appears to be largely excreted in the feces, primarily via biliary excretion. Renal excretion accounts for 0.05% to 0.5% of drug elimination.

**Half life:** The elimination half life of parent compound is 3.5 to 5 hours.

### 5.3 Preclinical Safety Data

Preclinical data reveal no special hazard for humans based on conventional studies of local or systemic toxicity, mutagenicity, carcinogenicity and toxicity reproduction.

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 4 hrs after administration, followed by a decline to a factor of 0.4 by 24 hrs.

## **6.0 Pharmaceutical Particulars**

### **6.1 List of Excipients**

Methyl  
Hydroxybenzoate  
Propyl  
Hydroxybenzoate  
Cetosteryl Alcohol  
Cetomacrogol 1000  
Light Liquid Paraffin  
White Soft Parafin  
Phosphoric Acid  
Purified Water

### **6.2 Incompatibilities**

Not applicable.

### **6.3 Shelf Life**

36 months

### **6.4 Special Precautions for Storage**

Store under normal storage conditions (15°C to 30°C). Do not freeze.

### **6.5 Nature and Contents of Container**

A White colour smooth Cream filled in 15 gm aluminium collapsible tube. Such 1 tube is packed in a Printed Carton with Packing Insert.

### **6.6 Special precaution for disposal and other handling**

Any unused product or waste material should be disposed of in accordance with local requirements.

## **7.0 Marketing Authorization Holder And Manufacturing Site Addresses**

### **Name and Address of Marketing Authorization Holder Lincoln Pharmaceuticals Limited**

Trimul Estate, Khatraj, Taluka: Kalol,

District: Gandhinagar Gujarat, India.

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## **8.0 Marketing Authorization Number**

CTD11276

## **9.0 Date of First <Registration> / Renewal of The <Registration>**

10/10/2025

## **10.0 Date of Revision of the Text**

22/11/2025

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