



## **1.3.1**

# **Summary of Product Characteristics (SmPC)**

## Module-1 Administrative Information and Product Information

### 1. Name of the medicinal Product

#### 1.1 Name of the medicinal Product

Clotrimazole Vaginal Cream USP 2%w/w

#### 1.2 Strength

Composition:

Clotrimazole USP 2%w/w

Cream Base Q.S.

### 2. Qualitative and Quantitative Composition

#### 2.1 Qualitative Declaration

Clotrimazole USP

#### 2.2 Quantitative Declaration

Sr. No.	Ingredients	Specifications	Standard Quantity (%W/W)	Reason for Inclusion
1	Clotrimazole (A)	USP	2.00	Antifungal
2	Phosphoric acid	BP	0.04	Acidifying agent
3	Methyl Hydroxybenzoate (Methyl paraben)	BP	0.16	Preservative
4.	Propyl Hydroxybenzoate (Propyl paraben)	BP	0.08	Preservative
5.	Cetostearyl Alcohol	BP	7.00	Viscosity-increasing agent
6.	Cetomacrogol 1000	BP	2.00	Surfactant
7.	Light Liquid Paraffin	BP	6.00	Emollient
8.	White Soft Paraffin	BP	16.00	Emollient
9.	Purified Water	BP	Q.S.	Solvent

## **Module-1 Administrative Information and Product Information**

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### **3. Pharmaceutical Form**

Semi Solid Dosage Forms. Cream

White colour smooth Cream filled in 30 gm aluminium collapsible tube.

### **4. Clinical Particulars**

#### **4.1 Therapeutic Indications**

Clotrimazole 2% Cream is recommended for the treatment of Vulvovaginal Candidiasis (VVC). It is use for relief of the symptoms like vaginal pruritus and burning associated with VVC; external vulvar itching and irritation associated with Vulvovaginitis.

It is also use for the treatment of mixed vaginal infections, including bacterial and Trichomonal etiologies, as an adjuvant therapy.

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

Once daily, preferably in the evening for three successive days, one applicator should be filled with cream (approx. 5 g) and inserted as deeply as possible into the vagina with the patient lying on her back.

##### **Directions for Insertion of vaginal cream using the applicator:**

Remove the cap from the tube and attach the applicator in its place. (See Figure-1)

Squeeze the tube from the bottom to fill the cream into the cylinder and push out the plunger as far out till the cylinder is filled. (See Figure-2)

Always roll the tube from the bottom to allow easy filling of the Applicator and complete utilisation of the contents.

Remove the filled Applicator from the tube and close the tube with the cap.

Hold the filled Applicator by the cylinder and gently insert the Applicator into the Vagina as deeply as possible. Press the plunger completely to empty the contents of the Applicator. With the plunger still depressed, remove the Applicator from vagina, holding it by the cylinder. (See Figure-3).

Insertion can be carried out more easily when lying on the back with the knees bent and spread out.

The Applicator after each use should be taken apart for cleaning by holding the cylinder with one hand and pulling out the plunger with slight force. Wash with soap and lukewarm water



## **Module-1 Administrative Information and Product Information**

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(not boiling water). Rinse thoroughly & dry them. To reassemble the Applicator, insert the plunger into the cylinder.

Note: Pregnant women should strictly follow the doctor's instructions.

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

Lactation: Excretion of Clotrimazole in breast milk is unknown. Clotrimazole vaginal formulations should be used, only if clearly needed.

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

There are no known significant interactions.

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

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

Lactation: Excretion of Clotrimazole in breast milk is unknown. Clotrimazole vaginal formulations should be used, only if clearly needed.

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

No studies on the effects on the ability to drive and use machines have been performed.

### **4.8 Undesirable Effects**

Local reactions: irritation, redness and burning may occurs.

### **4.9 Overdose**

## **Module-1 Administrative Information and Product Information**

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Clotrimazole is well-tolerated and there is no evidence of significant systemic absorption. In case of accidental ingestion, gastro-intestinal disturbances and central nervous system depression may occur.

Treatment: Treatment is symptomatic and supportive. In the event of accidental oral ingestion routine measures such as gastric lavage should be performed only 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.

### **5. Pharmacological Properties**

#### **5.1 Pharmacodynamics Properties**

Non-steroidal Anti-inflammatory and Analgesic

Clotrimazole is an imidazole derivative with a broad antimycotic spectrum of action in vitro and in vivo, which includes dermatophytes, yeasts, moulds, etc. Clotrimazole acts against fungi by inhibiting ergosterol synthesis. Inhibition of ergosterol synthesis leads to structural and functional impairment of the cytoplasmic membrane. The mode of action of clotrimazole is fungistatic or fungicidal depending on the concentration of clotrimazole at the site of infection.

#### **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**

Not Applicable

### **6 Pharmaceutical Particulars**

#### **6.1 List of Excipients**

Methyl Hydroxybenzoate BP

Propyl Hydroxybenzoate BP



## **Module-1 Administrative Information and Product Information**

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Cetosteryl Alcohol BP  
Cetomacrogol 1000 BP  
Light Liquid Paraffin BP  
White Soft Paraffin BP  
Phosphoric Acid BP  
Purified Water BP

### **6.2 Incompatibilities**

None.

### **6.3 Shelf Life**

36 months

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

Store below 30<sup>0</sup>C. Do not Freeze.

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

White colour smooth cream filled in 30 gm aluminum collapsible tube. Such 1 tube is packed in a printed carton along with a package 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. Registrant (Marketing Authorization Holder And Manufacturing Site Addresses)**

### **7.1 Name and Address of Marketing Authorization Holder**

**GENERICS AND SPECIALITIES LTD.**

31, AWONIYI ELEMOS STREET,  
OFF LATEEF SALAMI STREET.  
AJAO ESTATE, LAGOS,  
NIGERIA.

E-mail: [info@zolonhealthcare.com](mailto:info@zolonhealthcare.com)



## **Module-1 Administrative Information and Product Information**

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### **7.2 Name and Address of manufacturing site(s)**

Lincoln Pharmaceuticals Limited  
Trimul Estate, Khatraj, Taluka: Kalol,  
District: Gandhinagar Gujarat, India.  
Telephone no.: +91-07949-135000  
Fax: +91-07941-078062  
Email: [info@lincolnpharma.com](mailto:info@lincolnpharma.com)  
Website: [www.lincolnpharma.com](http://www.lincolnpharma.com)

### **7.3 Marketing Authorization Number**

To be included after obtaining first registration.

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

It will be applicable after registration of this product.

### **8. Date of Revision of the Text**

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### **9. Dosimetry (If Applicable)**

Not Applicable

### **10. Instructions for preparation of radiopharmaceuticals (if Applicable)**

Not Applicable