

**PRODUCT NAME**  
**GLOWCID CREAM**

(Clobetasole Propionate & Clotrimazole Cream)

**SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)**

## 1. Name of the medicinal product

**GENERIC NAME:** - Clobetasole Propionate , Clotrimazole Cream

**BRAND NAME -** GLOWCID

## 2. Qualitative and quantitative composition

Composition

Each gram Contains:

Clobetasol Propionate USP	0.05% w/w
Clotrimazole BP	1.0 w/w
Cream Base	Qs.

## 3. Pharmaceutical form

Cream

A smooth white cream.

## 4. Clinical particulars

### 4.1 Therapeutic indications

Clobetasole Propionate , Clotrimazole Cream **Treats fungal skin infections** and is a combination of two medicines, namely: Clobetasol and Clotrimazole. Clobetasol is a highly potent corticosteroid with anti-inflammatory, antipruritic (relieves itching) and vasoconstrictive (narrows blood vessels) properties.

### 4.2 Posology and method of administration

#### Posology

There is no separate dosage schedule for the young or elderly.

#### Method of administration

is for external use only. **Use this medication on the skin only as advised by the doctor.** Common side effects of CLOBETASOL+CLOTRIMAZOLE+FUSIDIC ACID are burning, irritation, itching, redness and thinning of skin at the application site.

### 4.3 Contraindications

is contraindicated in fungal, viral, protozoa infections, liver, kidney diseases, glaucoma, cataract, poor blood circulation, immune system problems, diabetes and adrenal gland diseases.

### 4.4 Special warnings and precautions for use

with proper consultation and caution. Do not use CLOBETASOL+CLOTRIMAZOLE on the face and avoid contact with eyes, nose and throat. Rinse it off with water thoroughly if you get the cream in these areas.

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

Clobetasole Clotrimazole Cream is contraindicated in fungal, viral, protozoa infections, liver, kidney diseases, glaucoma, cataract, poor blood circulation, immune system problems, diabetes and adrenal gland diseases.

## 4.6 Fertility, pregnancy and lactation

### Pregnancy:

CLOBETASOL+CLOTRIMAZOLE may be unsafe to use during pregnancy since it affects the baby. Please consult your doctor if you are planning to become pregnant or already pregnant before starting

### **Lactation:**

If your doctor says you need to, you can use clobetasol products while you are breastfeeding. It is not known how much passes into breast milk but it's likely to be a tiny amount.

### **Fertility:**

CLOBETASOL+CLOTRIMAZOLE+NEOMYCIN belongs to a class of dermatological medication 'Topical Anti-Infectives with Corticosteroids' used to treat fungal and bacterial infections of the skin. Also, CLOBETASOL+CLOTRIMAZOLE+NEOMYCIN helps to reduce swelling, itching, and redness caused due to certain skin problems.

### **4.7 Effects on ability to drive and use machines**

Clobetasol Propionate and Clotrimazole Cream has no or negligible influence on the ability to drive or use machines.

### **4.8 Undesirable effects**

Burning, stinging, itching, dryness, or redness at the application site may occur when first applied to the skin. This should disappear in a few days as your body adjusts to the medication. If any of these effects last or get worse, notify your doctor or pharmacist promptly.

### **Reporting of suspected adverse reactions**

When using clotrimazole to treat vulvovaginal candidiasis, <10% of patients have a **vulvar or vaginal burning sensation**. Other side effects include rash, hives, blisters, burning, itching, peeling, redness, swelling, pain, or other signs of skin irritation.

### **4.9 Overdose**

#### **Clobetasol Propionate**

Acute overdose is very unlikely to occur, however, in the case of chronic overdose or misuse, the features of hypercortisolism may appear and in this situation topical steroids should be reduced or discontinued gradually, under medical supervision. symptoms do not improve within a few days, or if they become worse, check with your doctor. Using too much of this medicine or using it for a long time may increase your risk of having adrenal gland problems. The risk is greater for children and patients who use large amounts for a long time.

#### **Clotrimazole**

If you use too much clotrimazole cream, spray or solution or use it more often than you need to, it may make your skin irritated or red. If this happens, use less the next time.

## **5. Pharmacological properties**

### **5.1 Pharmacodynamic properties**

#### **Mechanism of Action**

#### **Clobetasol Propionate**

The short term effects of corticosteroids are decreased vasodilation and permeability of capillaries, as well as decreased leukocyte migration to sites of inflammation.<sup>5</sup>Corticosteroids binding to the glucocorticoid receptor mediates changes in gene expression that lead to multiple downstream effects over hours to days. Glucocorticoids inhibit neutrophil apoptosis and demargination; they inhibit phospholipase A<sub>2</sub>, which decreases the formation of arachidonic acid derivatives; they inhibit NF-Kappa B and other inflammatory transcription factors; they promote anti-inflammatory genes like interleukin-10. Lower doses of corticosteroids provide an anti-inflammatory effect, while higher doses are immunosuppressive. High doses of glucocorticoids for an extended period bind to the mineralocorticoid receptor, raising sodium levels and decreasing potassium levels

### **Clotrimazole**

Clotrimazole acts primarily by damaging the permeability barrier in the cell membrane of fungi. Clotrimazole causes inhibition of ergosterol biosynthesis, an essential constituent of fungal cell membranes. If ergosterol synthesis is either completely or partially inhibited, the cell is no longer able to construct an intact and functional cell membrane<sup>1</sup>Because ergosterol directly promotes the growth of fungal cells in a hormone-like fashion, rapid onset of the above events leads to dose-dependent inhibition of fungal growth. Though decreased ergosterol, due to the inhibition of lanosterol 14-demethylase (also known as *CYP51*) is accepted to be primarily responsible for the antimycotic properties of clotrimazole, this drug also shows other pharmacological effects. These include the inhibition of sarcoplasmic reticulum Ca<sup>2+</sup>-ATPase, depletion of intracellular calcium, and blocking of calcium-dependent potassium channels and voltage-dependent calcium channels. The action of clotrimazole on these targets accounts for other effects of this drug that are separate from its antimycotic activities

### **Pharmacodynamic Effects**

#### **Clobetasol Propionate**

Corticosteroids bind to the glucocorticoid receptor, inhibiting pro-inflammatory signals, and promoting anti-inflammatory signals. Clobetasol propionate is generally applied twice daily so the duration of action is long. Corticosteroids have a wide therapeutic window as patients may require doses that are multiples of what the body naturally produces. Patients taking corticosteroids should be counselled regarding the risk of hypothalamic-pituitary-adrenal axis suppression and increased susceptibility to infections

#### **Clotrimazole**

Clotrimazole is a broad-spectrum antifungal agent that inhibits the growth of pathogenic yeasts by changing the permeability of cell membranes. The action of clotrimazole is fungistatic at concentrations of drug up to 20 mcg/mL and may be fungicidal *in vitro* against *Candida albicans* and other species of the genus *Candida* at higher concentrations. Unfortunately, resistance to clotrimazole, which was rare in the past, is now common in various patient populations. Clotrimazole is generally considered to be a fungistatic, and not a fungicidal drug, although this contrast is not absolute, as clotrimazole shows fungicidal properties at higher concentrations.

## **5.2 Pharmacokinetic properties**

May cause atrophic changes in the skin e.g. skin thinning, striae and dilatation of superficial blood vessels. Pigmentation and hypertrichosis. If there is substantial systemic absorption, neomycin may prolong and intensify respiratory depressant effects of neuromuscular blockers.

## **5.3 Preclinical safety data**

Non-clinical data reveal no special hazard for humans based on studies of repeated dose toxicity, genotoxicity and carcinogenicity. Clobetasol Propionate Clotrimazole Cream 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. Clobetasol Propionate Clotrimazole Cream 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. Pharmaceutical particulars**

### **6.1 List of excipients**

Cetostearyl Alcohol, CM 1000, Propyl Glycol Plain, LLP

### **6.2 Incompatibilities**

Not applicable

### **6.3 Shelf life**

36 months

### **6.4 Special precautions for storage**

Store in a cool dark place.

### **6.5 Nature and contents of container**

Lami tube with cap.

Pack sizes: 30GM

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

No special requirements

## **7.0 EXPORTER**

TRIOPLUS PHARMACEUTICALS PVT. LTD.  
106, Samruddhi commercial complex, Mindspace,  
Malad (west), Mumbai – 400064  
+91 9833905895  
+91 22 49705095

## **8.0 MANUFACTURER**

SYSTOCHEM LABORATORIES LTD.,  
B-75, Roop Nagar Industrial Area, Loni,  
Ghaziabad (UP)- 201102

## **9.0 MARKETING AUTHORITY**

SUITELIFE PHARMACEUTICAL LTD.  
4, Ayo Davies Close, Off Ekolou Street,  
Surulere, Lagos, Nigeria..