

## **1.3 Product Information**

### **1.3.1 Summary of Product Characteristics (SmPC) - Enclosed**

## Betasol Plus Cream

(Clobetasol Propionate, Ketoconazole and Neomycin Sulfate Cream 15 g & 30 g)

## 2. SUMMARY OF PRODUCT CHARACTERISTICS

### 1. NAME OF THE MEDICINAL PRODUCT

**Betasol Plus Cream** (Clobetasol Propionate, Ketoconazole and Neomycin Sulfate Cream 15 g & 30 g)

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Sr. No.	Name of constituent	Quantity per 15 g tube in mg	Quantity per 30 g tube in mg
1	Clobetasol Propionate USP	3.75	7.5
2	Ketoconazole (micronized) USP	150	300
3	Neomycin Sulphate BP	141.8	283.6
4	Cetomacrogol 1000 BP	450	900
5	Cetostearyl Alcohol BP	1200	2400
6	Methyl Hydroxy Benzoate BP	22.5	45
7	Propyl Hydroxy Benzoate BP	7.5	15
8	White Soft Paraffin BP (White Petroleum Jelly)	1500	3000
9	Parachloro Meta Cresol (Chlorocresol) BP	5.7	11.4
10	Propylene Glycol BP	750	1500
11	Anhydrous Sodium Sulphite BP	37.5	75
12	Sodium Dihydrogen Phosphate Dihydrate BP	3.78	7.56
13	Carrot Fragrance 120314 IH	90	180
14	Purified Water (q.s.) BP	q.s.	q.s.

#### Definitions:

USP: United States Pharmacopoeia

BP: British Pharmacopoeia

IH: In House Specification

### 3. PHARMACEUTICAL FORM

Cream

### 4. CLINICAL PARTICULARS

#### 4.1 Therapeutic indications

Local therapy for mycotic infections eg, tinea manuum, tinea corporis, tinea inguinalis, tinea cruris and tinea versicolor. It is also effective in the treatment of dermatitis, eczema and pruritis.

#### 4.2 Posology and method of administration

Apply externally to the affected area 2 times a day. Ordinary tinea corporis, inguinalis: 2 weeks; tinea pedis, tinea manum: 4 weeks.

Children: Not recommended for children.

## **Betasol Plus Cream**

(Clobetasol Propionate, Ketoconazole and Neomycin Sulfate Cream 15 g & 30 g)

### **4.3 Contraindications**

Betasol Plus Cream is contraindicated in patients with known hypersensitivity to any of its active ingredients; Pyrrolidine drugs, Ampyrimine drugs and Adrenocorticoids. It is not for ophthalmic use.

### **4.4 Special warnings and precautions for use**

When used on the face or large area of skin, application should be under the supervision of a physician. Betasol Plus Cream is not a cosmetic and, therefore, it cannot be used as a cosmetic. The product can be used in the armpit and groin under the supervision of a medical doctor. Avoid contact with eyes and mucous membranes. Pregnancy & lactation: To be used with caution.

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

None

### **4.6 Pregnancy and lactation**

To be used with caution.

### **4.7 Adverse Reactions**

When locally applied, weak side effects occur occasionally eg, hot and irritating feeling. Generally, there is no need to stop therapy. If there is no relief of symptoms or they get worse, you should stop with the application and see a physician. Erythema, burning, itching, sharp pain, folliculitis, skin atrophy, capillary ectasia, etc, are sometimes seen. Increase in skin dryness, pilosis polytrichia, striae atrophicae and infectious susceptibility can be observed. Adrenocortical hyperfunction can be induced by long term usage. The symptoms include pilosis polytrichia, acne, moon face, osteoporosis, etc. Allergic contact dermatitis can be occasionally seen.

### **4.8 Symptoms of Overdosage & Treatment**

There are no reports on overdosage.

## **5. PHARMACOLOGICAL PROPERTIES**

Pharmacological category: Clobetasol and antibiotics; Belongs to the class of very potent (group IV) corticosteroids, in combination with antibiotics.

Pharmacological action: Clobetasol Propionate is a cortex hormone that has high and effective anti-inflammatory and vasoconstrictive properties. Ketoconazole can selectively inhibit the cytochromes P-450 activity of fungi. Therefore, the biosynthesis of Ergosterol on the cell membrane is inhibited. It has extremely potent anti-mycotic actions against dermatophytes and

## Betasol Plus Cream

(Clobetasol Propionate, Ketoconazole and Neomycin Sulfate Cream 15 g & 30 g)

yeasts (Candidiasis, Pityrosporum sabour, Torulopsis, Cryptococcus), Histoplasmosis capsulalum, Eumycetes. However the product has weak inhibitory action to Aspergillus, Sporothrix schenckii, Dematiaceous fungi and Mucor except for Entomophthorales. Neomycin Sulfate is an aminoglycoside antibiotic for external use that is effective against gram-positive coccus and gram-negative bacillus.

Pharmacotherapeutic Group: ATC code: D07CD01 - Clobetasol and antibiotics; Belongs to the Class of very potent (group IV) corticosteroids, in combination with antibiotics.

### 5.1 Pharmacodynamic properties

Clobetasol Propionate is a cortex hormone that has high and effective anti-inflammatory and vasoconstrictive properties. Ketoconazole can selectively inhibit the cytochromes P-450 activity of fungi. Therefore, the biosynthesis of Ergosterol on the cell membrane is inhibited. It has extremely potent anti-mycotic actions against dermatophytes and yeasts (Candidiasis, Pityrosporum sabour, Torulopsis, Cryptococcus), Histoplasmosis capsulalum, Eumycetes. However the product has weak inhibitory action to Aspergillus, Sporothrix schenckii, Dematiaceous fungi and Mucor except for Entomophthorales. Neomycin Sulfate is an aminoglycoside antibiotic for external use that is effective against gram-positive coccus and gram-negative bacillus.

### 5.2 Pharmacokinetic properties

Clobetasol Propionate is be completely absorbed through the skin. The administered dose is metabolized, primarily in the liver. And it is excreted by kidney. Ketoconazole when applied topically to chest, back and arms of healthy adults with intact skin does not result in detectable blood concentrations. (Detectable Limit is less than 5ng/ml) during the first 72 hours. Neomycin Sulfate is not absorbed to any appreciable extent from intact skin. However, it is readily absorbed through denuded or abraded areas of skin or skin that has lost the keratin layer (i.e., wounds, burns, ulcers).

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

<b>Name of Excipients</b>
Clobetasol Propionate USP
Ketoconazole (micronized) USP
Neomycin Sulphate BP
Cetomacrogol 1000 BP
Cetostearyl Alcohol BP
Methyl Hydroxy Benzoate BP
Propyl Hydroxy Benzoate BP
White Soft Paraffin BP (White Petroleum Jelly)
Parachloro Meta Cresol (Chlorocresol) BP

**Betasol Plus Cream**

(Clobetasol Propionate, Ketoconazole and Neomycin Sulfate Cream 15 g & 30 g)

Propylene Glycol BP
Anhydrous Sodium Sulphite BP
Sodium Dihydrogen Phosphate Dihydrate BP
Carrot Fragrance 120314 IH
Purified Water (q.s.) BP

**6.2 Incompatibilities**

None.

**6.3 Shelf life**

36 months

**6.4 Special precautions for storage**

Do not store above 30°C. Protect from sunlight. Keep out of reach of children.

**6.5 Nature and contents of container**

15 gm & 30 gm collapsible aluminium tube.

**7. MARKETING AUTHORISATION HOLDER**

M/s SHALINA HEALTHCARE DMCC

Physical and Postal Address:

30th Floor, Almas Towers,

Jumeirah Lakes Towers Dubai-UAE.

Country: Dubai