

**MODULE 1- ADMINISTRATIVE PARTICULARS OF THE PRODUCT****1.3 Product Information****1.3.1 Summary of Product Characteristics (SmPC)****1.3.1.1. Name of the medicinal product:****1.1 (Invented) name of the medicinal product:****Generic Name/INN Name:**

Ketoconazole, Clobetasol Propionate, Neomycin Sulphate and Vitamin E Cream

**Brand Name:**

DEDERM CREAM

**1.2 Strength:**

Each gm contains:

Ketoconazole USP ..... 1.0 % w/w

Clobetasol Propionate USP .....0.025 % w/w

Neomycin Sulfate USP Equivalent to Neomycin .....0.50 % w/w

Vitamin E USP ..... 1.0 % w/w

Cream Base ..... q.s.

**1.3 Pharmaceutical form:**

Semi Solid Dosage form- Cream (Topical Use)

**2. Qualitative and Quantitative Composition:**

Sr. No.	Ingredients	Spec	Label Claim (% w/w)	Std. Qty./ 1gm (mg)	% w/w	Function
<b>Drug Preparation</b>						
1.	Ketoconazole*	USP	1.00%	10.000	1.000	Active Pharmaceutical Ingredient
2.	Clobetasol propionate*	USP	0.025%	0.250	0.025	Active Pharmaceutical Ingredient
3.	Neomycin sulfate eq. to Neomycin*	USP	0.50%	5.000	0.500	Active Pharmaceutical Ingredient
4.	Vitamin E *	USP	1.00%	10.000	1.000	Active Pharmaceutical Ingredient
<b>Oil Phase</b>						
5.	Cetostearyl alcohol	BP	-	80.000	8.000	Emulsifying

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						agent
6.	Light Liquid Paraffin	BP	-	80.000	8.000	Emollient
7.	White soft Paraffin	BP	-	168.000	16.800	Emollient
8.	Butylated Hydroxytoluene	BP	-	0.900	0.090	Preservative
<b>Aqueous Phase</b>						
9.	Cetomacrogol 1000	In-House	-	20.000	2.000	Emulsifying agent
10.	Chlorocresol	BP	-	1.000	0.100	Preservative
11.	Propylene Glycol	BP	-	80.000	8.000	Humectant/Co-solvent
12.	Purified Water**	BP	-	544.850	54.485	Vehicle
<b>Total Weight</b>				<b>1000.000</b>	<b>100.000</b>	

**Note:** \* The quantity of the Ketoconazole, Clobetasol Propionate, Neomycin Sulfate and Vitamin E has to be calculated as per the Assay and LoD.

\*\* Quantity of Purified Water will vary as per the quantity of the APIs.

**3. Pharmaceutical form:**

**Dosage Form:** Semi Solid Dosage form- Cream (Topical Use)

**Visual & Physical characteristics of the product:** A white to off-white colored smooth structured cream filled in Lamitube.

**4. Clinical particulars:****4.1 Therapeutic indications:**

Ketoconazole, Clobetasol Propionate, Neomycin Sulfate and Vitamin E Cream is indicated in the treatment for the topical treatment of fungal infections of the skin including: Tinea Cruris. Tinea Corporis; tinea manus, tinea pedis.

**4.2 Posology and method of administration:****Posology**Adults

Apply to the affected area two or three times daily. Generally, the duration of application depends on the type of infecting organism.

Treat as below for the following:

Tinea corporis 2 weeks.

Tinea Cruris 2 weeks.

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Tinea Manuum 4 weeks.

Tinea Pedis 4 weeks.

### Paediatric population

Ketoconazole, Clobetasol Propionate, Neomycin Sulfate and Vitamin E Cream is not recommended for children under the age of two years.

**Method of administration:** Topical administration only.

### **4.3 Contraindications:**

Hypersensitivity to the active substance or to any of the excipients being used in this formulation. This cream is for topical use only and cannot be used for internal or ophthalmic use.

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

- Avoid contacting with eyes.
- Patients with tinea cruris avoid wearing underwear that is tight-fitting or made from synthetic materials (e.g. rayon, nylon), Instead, wear loose-fitting, cotton underwear.
- Patient with tinea pedis avoids wearing socks made from wool or synthetic materials (for example, rayon or nylon). Instead, wear clean, cotton socks and change them daily or more often if your feet sweat a lot. Wear well-ventilated shoes.
- If your skin problem does not improve within 2-4weeks for cutaneous candidiasis, pityriasis versicolor, tinea corporis or tinea cruris; or 4 weeks for seborrheic dermatitis; or if it becomes worse. check with your doctor.
- This cream contains Clobetasol Propionate. If the product is administered for long term in large area or used with banding treatment it may induce the reversibility restraint of PHA axis. Cushing syndromes, hyperglycosemia, urinary glucose etc. can be occurred on some patients. So long term and large area using the product is not recommended. Banding treatments is not recommended too.
- The product can be used in the cockled skin of the face, armpit and groin under the supervision of a medical doctor.
- Combining with other skin infection, the anti-infective drugs should be administered. If the infection has not been controlled, stop using the product until the infection is controlled.
- When the local Ulcer and damage occur, Neomycin Sulfate is absorbed increasingly. The adverse reaction of aminoglycoside drug should be observed.

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

This cream as a topical cream dose not interacts with any other product.

### **4.6 Pregnancy and lactation:**

Pregnant and lactation women should be used with caution.

Large area and long term using is not recommended.

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

None.

### **4.8 Undesirable effects:**

- Erythema, burning, itch, sharp pain or other stimulus symptom, folliculitis, skin atrophy, Capillarectasis, etc are commonly seen.
- Skin dryness, pilosis polytrichia, striae atrophicae and infectious susceptibility increasing can be observed.
- Adrenocortical hyperfunction can be induced by long term using. The symptom includes pilosis polytrichia, acne, moon face, Osteoporosis. etc.
- Allergic contact dermatitis can be seen on occasion.

### **4.9 Overdose:**

This cream is well tolerated, no adverse effect has been observed in the event of overdosage.

## **5. Pharmacological properties:**

### **5.1 Pharmacodynamic properties:**

#### Mode of action

The active ingredient of this Cream is ketoconazole, a pyrrolidine antifungal agent. It has extremely potent anti-mycotic actions against dermatophytes and yeasts (candidiasis, Pityrosporum, sabour, Torulosis, Cryptococcus), histoplasmosis capsulalum. Eumycetes. However, the product has weak inhibitory action to Aspergillus. Sporothrix schenckii, dematiaceous fungi and mucor except for Entomophthorales.

Action mechanism of Ketoconazole: It can selectively inhibit the cytochromes P-450 activity of fungi. Therefore, the Biosynthesis of Ergosterol on the cell membrane inhibited. Clobetasol Propionate is a hormone of the cortex that is highly effective anti-inflammatory and cause capillary contraction. Neomycin Sulfate, external use aminoglycoside antibiotics, can treat local infection.

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The mechanism of vitamin E (alpha-tocopherol)-mediated low-density lipoprotein lipid peroxidation, it mainly inhibits the production of new free radicals.

### **5.2 Pharmacokinetic properties:**

Ketoconazole which is applied to the chest, back and buttocks of the healthy volunteers cannot be inspected in blood (Detectable Limit is less than 5mg/ml) during the first 7 hours. Clobetasol Propionate can be completely absorbed by dermal. The administered dose is metabolized, primarily in the liver. And it is excreted by kidney. Neomycin Sulfate can be rarely absorbed by derma. However, when the skin is ulcer and breakage it can be absorbed increasingly. Vitamin E easily absorbs into skin.

### **5.3 Preclinical safety data**

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections

## **6. Pharmaceutical particulars:**

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

Cetostearyl alcohol  
Light Liquid Paraffin  
White soft Paraffin  
Butylated hydroxytoluene  
Cetomacrogol 1000  
Chlorocresol  
Propylene Glycol  
Purified Water

### **6.2 Incompatibilities:**

Not applicable

### **6.3 Shelf life:**

24 months

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

Store at temperature not exceeding 30 °C. Do not freeze.

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

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**Ketoconazole, Clobetasol Propionate, Neomycin Sulphate and Vitamin E Cream**



## **Bharat Parenterals Limited**

**Registered Office & Works:**  
Vill. Haripura, Ta. Savli, Dist. Vadodara - 391520 (Guj.) India.  
Tele Fax : (02667)-251679, 251680, 251669, 99099 28332.  
E-mail: bplbrd@bplindia.in, info@bplindia.in, Web.: www.bplindia.in  
CIN NO: U24231GJ1992PLC018237

### **MODULE 1- ADMINISTRATIVE PARTICULARS OF THE PRODUCT**

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Packing Type: 20gm Lami tube

Packing Presentation: 20 gm of filled Lami tube is packed in monocarton along with package insert

#### **6.6 Special precautions for disposal:**

No special requirements.

#### **7. Applicant:**

**CHEZ RESOURCES PHARMACEUTICAL NIGERIA LIMITED,**

No. 7, Calabar Street, Fegge, Onitsha, Anambra State, NIGERIA.

#### **Name and Address of manufacturer:**

M/s. Bharat Parenterals Limited

Survey No. 144 - A, Jarod Samlaya Road,

Village: Haripura, Tal. Savli,

Dist.- Vadodara – 391520, Gujarat, India.

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