

## **1. NAME OF THE MEDICINAL PRODUCT**

Ketoconazole, Clobetasol Propionate and Neomycin sulfate Cream

## **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each grams contains:

Ketoconazole BP..... 10 mg

Clobetasol Propionate BP.....0.25 mg

Neomycin Sulfate USP .....5000 IU

cream base.....q.s.

For complete list of excipients refer section 6.1.

## **3. PHARMACEUTICAL FORM**

Topical, Semi-solid Dosage Form – Cream

Off white to dull pink coloured, soft homogenous cream, free from any gritty particles.

## **4. CLINICAL PARTICULARS**

### **4.1 Therapeutic indications**

SAICLONE PLUS is an antifungal, antibacterial, anti-inflammatory and antipruritic cream. It is indicated for topical treatment of fungal infections of the skin including Tinea Manus, Tinea Pedis, Tinea Corporis, Tinea Cruris, Tinea Versicolor, Dermatitis, Allergic reactions such as Eczema, Pruritus.

### **4.2 Posology and method of administration**

Apply to the affected area once a day, depending on the severity of the infection, the cream may be applied on the affected area twice daily when necessary. Generally the duration of application depends on the type of infecting organism; Treat as bellows for die following: Tinea Corporis 2 weeks; Tinea Cruris 2 weeks; Tinea Pedis 4 weeks; Tinea Manus 4 weeks. Infection normally resistant to antifungal agents 4-6 weeks.

### **4.3 Contraindications**

SAICLONE PLUS is contraindicated in patients with known hypersensitivity to any of its ingredients. It is for topical use only and cannot be used for internal or ophthalmic use. Special precautions must be observed during use on pregnant women and children.

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

For external use only.

Avoid contact with eyes.

Do not exceed prescribed dosage.

Read carefully before using.

### **Precautions**

Clinical studies of transcutaneous absorption conducted on animals and humans have proved that the reabsorption rate of ketoconazole cream is negligible; as such SAICLONE PLUS can be used in pregnancy under the supervision of a medical doctor. Application to the face or on large areas for longer periods of time than recommended in leaflet should be under a medical doctor's supervision.

### **4.5 Drug Interactions**

SAICLONE PLUS as a topical cream does not interact with any other product.

### **4.6 Pregnancy and Lactation**

Not available

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

Not available.

### **4.8 Undesirable effects**

SAICLONE PLUS is topical cream that is well tolerated and has little or no side effects when used properly. On occasion, irritation or burning sensation may occur during treatment. However, it is unnecessary to discontinue the treatment with ELBE SKINEO. In severe or extreme cases you may contact the doctor.

### **4.9 Overdose**

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

## **5. PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamics properties**

The active ingredient of SAICLONE PLUS is ketoconazole, an antifungal agent with a broad-spectrum of activity from the Imidazole group. SAICLONE PLUS has extremely potent anti-mycotic actions against dermatophytes, its spectrum of activity normally against following: Candida Albicans, Toulopsis, Cryptococcus, Pityrosporum.

Clobetasol Propionate is a hormone of the cortex that is highly effective as an anti-inflammatory and anti-allergenic agent with little or no side effects.

Neomycin sulfate is an aminoglycoside antibiotic which can treat local infection for external use. The synergies obtained in the composition of the compound results in the cream being highly effective against fungi, bacteria, inflammation and pruritus.

### **5.2 Pharmacokinetic properties**

### **5.3 Preclinical safety data**

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Cetomacrogol-1000, Cetostearyl Alcohol, Light liquid Paraffin, White soft paraffin, Propylene glycol, Disodium Hydrogen Phosphate Dihydrate, Sodium Dihydrogen Phosphate Dihydrate, Methyl Hydroxy Benzoate, Propyl Hydroxy Benzoate, Anhydrous Sodium Sulfate, Phosphoric acid, Fragrance spring awakening P4200, Purified water.

### **6.2 Incompatibilities**

Not Applicable

### **6.3 Shelf life**

36 months.

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

Store below 30°C in a dry place, Protect from light.

Do not freeze.

Do not accept if seal is broken.

Keep the tube tightly closed after use.

Keep the medicine out of reach of children

**6.5 Nature and contents of container <and special equipment for use, administration or implantation**

30g cream filled in lami tube with polypropylene cap packed in carton with pack insert.

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

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

**7. APPLICANT/MANUFACTURER**

M/S SAI SAGAR PHARMA LIMITED

2, KAARA STREET, OFF OSOLO WAY,

AJAO ESTATE, ISOLO,

LAGOS, LAGOS STATE NIGERIA

**Manufactured by:**



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