

**MAXHEAL**  
For Maximum Healing

<b>BRAND NAME:</b>	<b>SISKIN CREAM</b>
<b>GENERIC NAME:</b>	<b>KETOCONAZOLE, CLOBETASOL PROPIONATE &amp; NEOMYCIN SULPHATE CREAM</b>

**OUTER CARTON**



<b>BRAND NAME:</b>	<b>SISKIN CREAM</b>
<b>GENERIC NAME:</b>	<b>KETOCONAZOLE, CLOBETASOL PROPIONATE &amp; NEOMYCIN SULPHATE CREAM</b>

**LEAFLET**



periods of time than recommended in Leaflet should be under the supervision of a physician.

**INTERACTIONS:**  
 Because little, if any of ketoconazole cream is absorbed into the blood, the risk of it, interacting with another medicine is low. Caution should be exercised when using drugs like Carbamazepine, Cyclosporine and oral hypoglycemic agents especially patient with extensive skin damage whereby there may be increased absorption. Neomycin also may impair the absorption of drugs like digoxin, methotrexate, some vitamins and oral contraceptive in such instance.

**ADVERSE EFFECTS:**  
 SISKIN Cream is a Topical antifungal cream that is well tolerated and has little or no side effects when used properly on occasions irritations or burning sensation may occur during treatment. However unnecessary to discontinue treatment with SISKIN cream in severe or extreme cases you may contact the doctor. Clobetasol may interact with anticoagulants, anticonvulsants antidiabetics and Non-steroidal anti-inflammatory agents when used on the damaged skin.

**DOSAGE AND ADMINISTRATION:**  
 Wash the affected area with soap water & dry with clean cloth. Apply SISKIN Cream over the affected area. Repeat the application after every three hours. 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, Tinea pedis, 4 weeks, Tinea manus: 4 weeks, infection normally resistant to antifungal agents; 4 to 6 weeks.

**SYMPTOMS OF OVERDOSE AND TREATMENT:**  
 SISKIN Cream is well tolerated, no adverse effect has been observed in the event of over dosage.

**PRESENTATION:** 30 g tube.

**SHELF-LIFE:** Three years.

**STORAGE:** Store in a well closed container and avoid prolonged exposure to excessive heat.

**Keep all medicines out of reach of children.**

Mfg Lic. No.: KD-401 NAFDAAC Reg No.: 84-6772

Manufactured in India by:  
**MAXHEAL Pharmaceuticals (India) Ltd.**  
 R.D.-20, Bhandari Road, Bangal Nagar, Gurgaon (H), Haryana - 122008.  
 Factory: A-7, 3rd D.C. Transport Industrial Area, Sector - 40/1 GZG,  
 The Moolchand Estate, Gurgaon (H).

Marketed by:  
**Maydon Pharmaceuticals Ltd.**  
 15, Wilmar Street, Off Toan Planning Way,  
 3rd Flr., Lagos, Nigeria.  
 Contact - 00197665587 | maydonpharma@yahoo.com

MAYDON PHARMACEUTICALS

**MAXHEAL**

For Maximum Healing

<b>BRAND NAME:</b>	<b>SISKIN CREAM</b>
<b>GENERIC NAME:</b>	<b>KETOCONAZOLE, CLOBETASOL PROPIONATE &amp; NEOMYCIN SULPHATE CREAM</b>

**TUBE**





<b>BRAND NAME:</b>	<b>SISKIN CREAM</b>
<b>GENERIC NAME:</b>	<b>KETOCONAZOLE, CLOBETASOL PROPIONATE &amp; NEOMYCIN SULPHATE CREAM</b>

### **1.3 PRODUCT INFORMATION**

#### **1.3.1 SUMMARY OF PRODUCT CHARACTERISTICS (SMPC)**

Enclosed

<b>BRAND NAME:</b>	<b>SISKIN CREAM</b>
<b>GENERIC NAME:</b>	<b>KETOCONAZOLE, CLOBETASOLE PROPIONATE &amp; NEOMYCIN SULPHATE CREAM</b>

**1. Name of drug product**

KETOCONAZOLE, CLOBETASOL AND NEOMYCIN CREAM

**1.1 (Trade) name of product**

SISKIN CREAM

**1.2 Strength**

Each gram Contains:

Ketoconazole USP.....10 mg

Clobetasol Propionate USP....0.25 mg

Neomycin Sulphate USP.....5000 IU

Cream Base.....Q.S.

**1.3 Pharmaceutical Dosage Form**

Cream

<b>BRAND NAME:</b>	<b>SISKIN CREAM</b>
<b>GENERIC NAME:</b>	<b>KETOCONAZOLE, CLOBETASOLE PROPIONATE &amp; NEOMYCIN SULPHATE CREAM</b>

## 2. QUALITATIVE & QUANTITATIVE COMPOSITION

### 2.1 Qualitative Declaration

#### SISKIN CREAM

Each gram Contains:

Ketoconazole USP.....10 mg

Clobetasol Propionate USP....0.25 mg

Neomycin Sulphate USP.....5000 IU

Cream Base.....Q.S.

### 2.2 Quantitative Declaration

#### Batch Formula:

**Batch Size: 750 Kgs**

S. No.	Name of the ingredients	Reference Standards	Function	Label Claim	Quantity per unit dose
1.	Clobetasol Propionate	USP	Active	0.25 mg	0.188 Kg
2.	Ketoconazole	USP	Active	10 mg	7.500 Kg
3.	Neomycin Sulphate	USP	Active	5000 IU	5.364 Kg
4.	Chlorocresol	BP	Preservative	---	0.750 Kg
5.	Cetostearyl Alcohol	BP	Emulsion Stabilizer	---	56.250 Kg
6.	Cetomacragol 1000	BP	Emulsifier	---	15.000 Kg
7.	Light Liquid Paraffin	BP	Soothing Agent	---	37.500 Kg
8.	White Soft Paraffin	BP	Soothing Agent	---	93.750 Kg
9.	Isopropyl Myrisate	BP	Moisturizer	---	15.000 Kg
10.	B.H.T.	BP	Antioxidant	---	0.458 Kg
11.	Sodium Dihydrogen Phosphate	BP	Buffer	---	2.271 Kg
12.	Propylene Glycol	BP	Solvent	---	60.000 Kg
13.	Disodium EDTA	BP	Chelating Agent	---	0.750 Kg
14.	Purified Water	--	Cream Base	---	q. s.

<b>BRAND NAME:</b>	<b>SISKIN CREAM</b>
<b>GENERIC NAME:</b>	<b>KETOCONAZOLE, CLOBETASOLE PROPIONATE &amp; NEOMYCIN SULPHATE CREAM</b>

### **3. PHARMACEUTICAL DOSAGE FORM**

Cream

### **4. CLINICAL PARTICULARS**

#### **4.1 Therapeutic Indications**

SISKIN Cream is indicated for topical application in the treatment of fungal infection of skin, such as tinea manus, tinea pedis, tinea cruris, tinea corporis and tinea versicolor. It is also proved effective on the treatment of many kinds of der matitis, eczema and pruritus.

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

Wash the affected area with soap water & dry with clean cloth. Apply SISKIN Cream over the affected area. Repeat the application after every three hours. 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, Tinea pedis, 4 weeks, Tinea manus: 4 weeks, infection normally resistant to antifungal agents; 4 to 6 weeks.

#### **4.3 Contraindications**

SISKIN Cream is contraindicated in patients with known hypersensitivity to any of its. Ingredients. It is not for ophthalmic uses. Take special precautions in usage during pregnancy and infants.

#### **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.

Application to the face or on large areas for longer periods of time than recommended in Leaflet should be under the supervision of a physician.

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

Because little, if any of ketoconazole cream is absorbed into the blood, the risk of it. Interacting with another medicine is low. Caution should be exercised when using drugs like Carbamazepine,

<b>BRAND NAME:</b>	<b>SISKIN CREAM</b>
<b>GENERIC NAME:</b>	<b>KETOCONAZOLE, CLOBETASOLE PROPIONATE &amp; NEOMYCIN SULPHATE CREAM</b>

Cyclosporine and oral hypoglycemic agent's especially patient with extensive skin damage whereby there may be increased absorption.

Neomycin also may impair the absorption of drugs like digoxin, methotrexate, some vitamins and oral contraceptive in such instance.

#### **4.6 Fertility, pregnancy and lactation**

Adequate human data on use during pregnancy are not available.

Adequate human and animal data on use during lactation are not available.

#### **4.7 Effects on ability to drive and operate machine**

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

#### **4.8 Undesirable effects**

SISKIN Cream is a Topical antifungal cream that is well tolerated and has little or no side effects when used properly on occasions irritations or burning sensation may occur during treatment. However unnecessary to discontinue treatment with SISKIN cream in severe or extreme cases you may contact the doctor. Clobetasol may interacts with anticoagulants, anticonvulsants antidiabetics and Non-steroidal anti-inflammatory agents when used on the damaged skin.

#### **4.9 Overdose**

Acute overdosage with topical application of SISKIN CREAM is unlikely and would not be expected to lead to a life-threatening situation; however topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects.

Toxic effects are unlikely to occur following accidental ingestion of SISKIN CREAM. Signs of toxicology appearing after such accidental ingestion should be treated symptomatically.



<b>BRAND NAME:</b>	<b>SISKIN CREAM</b>
<b>GENERIC NAME:</b>	<b>KETOCONAZOLE, CLOBETASOLE PROPIONATE &amp; NEOMYCIN SULPHATE CREAM</b>

## **5. Pharmacological properties**

### **5.1 Pharmacodynamic properties**

Ketoconazole is a broad spectrum imidazole antifungal that interferes with ergosterol synthesis and therefore alters the permeability of the cell membranes of fungi. Pharmacological studies have shown that ketoconazole has extremely potent antimycotic actions against dermatophytes (such as *Trichophyton* sp., *Microsporum* sp. and *Epidemophyton* sp.), *Saccharomyces* and *Candida albicans*.

Strains of fungi are unlikely to have a natural resistance to ketoconazole.

Clobetasol is a corticosteroid used topically for its glucocorticoid activity in the treatment of various skin disorders. It is highly effective as anti-inflammatory, antiallergic agent with a few side effects.

Neomycin sulphate interferes with bacterial protein synthesis by binding to 30S ribosomal subunits. Neomycin sulphate has a bactericidal action against many Gram-negative bacteria but it lacks activity against *Pseudomonas aeruginosa*. It has partial activity against Grampositive bacteria. It is used topically in the treatment of infections of the skin, ear, and eye due to susceptible staphylococci and other organisms.

### **5.2 Pharmacokinetic properties**

Ketoconazole- Systemic absorption of ketoconazole following topical application is minimal.

Clobetasol-Topically applied clobetasol propionate can be absorbed through normal intact skin once absorbed through the skin, It is metabolized primarily in the liver and excreted by the kidneys and. to a lesser extent. In bile. Neomycin although not absorbed from intact skin, absorption may be increased in conditions which damage or inflame the mucosa Absorption has also been reported to occur from the peritoneum, respiratory tract, bladder, wounds and inflamed skin.

Once. Neomycin is absorbed it is rapidly excreted by the kidneys in active form. It has been reported to have a half-life of 2 to 3 Hours.

### **5.3 Pre-clinical safety data**

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



<b>BRAND NAME:</b>	<b>SISKIN CREAM</b>
<b>GENERIC NAME:</b>	<b>KETOCONAZOLE, CLOBETASOLE PROPIONATE &amp; NEOMYCIN SULPHATE CREAM</b>

## 6. Pharmaceutical particulars

### 6.1 List of excipients

Chlorocresol

Cetostearyl Alcohol

Cetomacragol 1000

Light Liquid Paraffin

White Soft Paraffin

Isopropyl Myrisate

B.H.T.

Sodium Dihydrogen Phosphate

Propylene Glycol

Disodium EDTA

Purified Water

### 6.2 Incompatibilities

Not Applicable

### 6.3 Shelf-Life

36 months

### 6.3 Special Precautions for Storage

Store in a well closed container and avoid prolonged exposure to excessive heat.

### 6.4 Nature and Contents of Container

30 gm Lami tube

## 7. Marketing authorization holder



**MAXHEAL PHARMACEUTICALS (INDIA) LTD.**

J-7, M.I.D.C, TARAPUR INDUSTRIAL AREA,

BOISAR-401506, DIST. PALGHAR, INDIA



<b>BRAND NAME:</b>	<b>SISKIN CREAM</b>
<b>GENERIC NAME:</b>	<b>KETOCONAZOLE, CLOBETASOLE PROPIONATE &amp; NEOMYCIN SULPHATE CREAM</b>

**8. Marketing authorisation number(s)**

NA

**9. Date of first authorisation/renewal of the authorization**

NA

**10. Date of revision of the text**

NA