

## **PACKAGE LEAFLET: INFORMATION FOR THE USER**

### **Betamethasone Dipropionate, Clotrimazole and Gentamicin Sulfate Cream SKDERM CREAM**

**Read all of this leaflet carefully because it contains important information for you.**

This medicine is available without prescription to treat minor conditions. However, you still need to use it carefully to get the best results from it.

- Keep this leaflet, you may need to read it again
- If you have any further questions, ask your doctor or pharmacist
- You must contact a doctor if your symptoms worsen or do not improve after 7 days
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in the leaflet. See section 4

#### **What is in this leaflet**

1. What SKDERM Cream is and what it is used for
2. What you need to know before you use SKDERM Cream
3. How to use SKDERM Cream
4. Possible side effects
5. How to store SKDERM Cream
6. Contents of the pack and other information

#### **1. What SKDERM Cream is and what it is used for**

SKDERM Cream contains the active ingredient Betamethasone Dipropionate USP equivalent to Betamethasone, Clotrimazole BP, Gentamicin Sulfate BP equivalent to Gentamicin Base.

Betamethasone Dipropionate is a medium-potency corticosteroid indicated for relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses. Clotrimazole is an antifungal agent. Gentamicin cream is a topical antibiotic. Clotrimazole and Betamethasone Dipropionate is a combination of Antibacterial, Antifungal and Corticosteroid.

All three of them in combination is indicated for the topical treatment of symptomatic inflammatory tinea pedis, tinea cruris, and tinea corporis due to *Epidermophyton floccosum*, *Trichophyton mentagrophytes*, *Trichophyton rubrum* and also in skin infections caused by certain bacteria.

## **2. What you need to know before you use SKDERM Cream**

### **Do not use SKDERM Cream**

- an allergy to Betamethasone Dipropionate USP equivalent to Betamethasone, Clotrimazole BP, Gentamicin Sulfate BP equivalent to Gentamicin Base or any of the other ingredients in this medicine (listed in section 6).

### Warnings and precautions

- Long-term continuous topical therapy should be avoided where possible, particularly in children, as adrenal suppression can occur even without occlusion. If infection persists systemic chemotherapy is required. Withdraw topical corticosteroid if there is a spread of infection. Bacterial infection is encouraged by the warm, moist conditions induced by occlusive dressings and the skin should be cleansed before a fresh dressing is applied. Avoid prolonged application on the face. The face more than other areas of the body, may exhibit atrophic changes after prolonged treatment with potent topical corticosteroids, this must borne in mind when treating such conditions as psoriasis discoid lupus erythematosus and severe eczema if applied to the eyelids, care is need to ensure that the preparation does not enter the eye as glaucoma might result. If Betamethasone Dipropionate + Clotrimazole + Gentamicin Sulphate Cream does enter the eye, the affected eye should be bathed, in copious amounts of water. Topical corticosteroids may be hazardous in psoriasis for a number of reasons including rebound relapses, development of tolerance, risk of generalized postular psoriasis and development of local or systemic toxicity due to impaired barrier function of the skin. If used in psoriasis careful patient supervision is important. Extended or recurrent application may increase the risk of contact sensitization. Extension of infection may occur due to the masking effect of the steroid. Following significant systemic absorption, aminoglycosides such as Gentamicin can cause irreversible ototoxicity; and Gentamicin has nephrotoxic potential. In renal impairment the plasma clearance of gentamicin is reduced. Products which contain antimicrobial agents should not be diluted.
- Excess use of this cream is not advisable unless it is recommended by physician.

### **Pregnancy, breast-feeding and fertility**

SKDERM CREAM is suitable to use in treatment of vaginal candidiasis during second and third trimester of pregnancy but, it should be avoided during First trimester as it may lead to fetal harm.

### **3. How to use SKDERM Cream**

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Betamethasone Dipropionate

Burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae, miliaria. skin atrophy (bruising, shininess). Skin atrophy occurred in 3 of 63 (5%) patients, a 3-year old, a 5-year old, and a 7-year old. Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria in some patients.

Clotrimazole: Dermatologic side effects have included erythema, stinging, blistering, peeling, edema, itching, burning, and general skin irritation. Contact dermatitis, confirmed by patch testing, has been documented. Genitourinary system effects associated with intravaginal use have included burning, itching, cramping, pain, and bleeding. Vulvar lesions and rash have rarely been reported.

Gentamicin: In patients with dermatoses treated with gentamicin sulfate, irritation (erythema and pruritis) that did not usually require discontinuance of treatment has been reported in a small percentage of cases. There was no evidence of irritation or sensitization, however, in any of these patients patch-tested subsequently with gentamicin sulfate on normal skin. Possible photosensitization has been reported in several patients but could not be elicited in these patients by reapplication of gentamicin sulfate followed by exposure to ultraviolet radiation.

## **5. How to store SKDERM Cream**

Do not store above 30°C.

Do not freeze.

Do not accept if seal is broken.

Puncture nozzle seal with piercing point of the cap.

Keep the medicine out of reach of children.

For external use only.

Do not use this medicine after the expiry date.

After this date return any unused product to your nearest pharmacy for safe disposal.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What SKDERM CREAM contains**

This cream contains Betamethasone Dipropionate USP equivalent to Betamethasone, Clotrimazole BP, Gentamicin Sulfate BP equivalent to Gentamicin Base, which are the active ingredient.

As well as the active ingredient, the cream also contains Chlorocresol, Cetomacrogol -1000, Cetostearyl Alcohol, Light Liquid Paraffin, White Soft Paraffin, Propylene Glycol, Disodium Hydrogen Phosphate (Dihydrate), Sodium Dihydrogen Phosphate Dihydrate, Disodium Edetate, Sodium Metabisulphite, Perfume Fern Lavender (P-1)

**Packing details:**

30 g Aluminium Collapsible tubes internally lacquered with epoxy phenol

15 g Aluminium Collapsible tubes internally lacquered with epoxy phenol

30g Lami tube with Alu peel off seal

15g Lami tube with Alu peel off seal

**Manufactured by:**



**Factory address: 1802-1805, G.I.D.C., Phase III,**

**Vapi - 396 195. Gujarat, INDIA.**

**Head office: 3 - A, Shivsagar Estate,**

**Dr. Annie Besant Road,**

**Worli, Mumbai 400 018, India**

**Tel.: 0091 - 22 - 6622 7575 (Board Line)**

**Fax.: 0091 - 22 - 6622 7500**

**Email: kalpesh@sk1932.com**