**SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. Name of the Medicinal Product:

CUTICOR (Betamethasone Dipropionate, Gentamicin & Clotrimazole Cream)

## 2. Quality and Quantitative Composition

Each g contains:
Betamethasone Dipropionate USP……0.64 mg
Gentamicin Sulphate BP……1.00 mg
Clotrimazole USP……10.00 mg In
cream base ……q.s.

**For Excipients see section 6.1**

## 3. Pharmaceutical Form

Topical Cream.

White colour cream.

## 4. Clinical Particulars

### 4.1 Therapeutic indications:

CUTICOR Cream is indicated for the topical treatment of mixed skin infection.

### 4.2 Posology and methods of administration:

Apply 2 to 3 times a day. The affected skin should be cleaned and dries, before the cream is applied.

### 4.3 Contraindications

Hypersensitivity to any of the ingredients.

### 4.4 Special warning and precautions for use:

Betamethasone dipropionate and clotrimazole should not be used in or near the eyes since this preparation is not formulated for ophthalmic use.

**Warning:**
Pregnancy:

There are no adequate and well-controlled studies in pregnant women on teratogenic effects of a topically applied combination of clotrimazole and betamethasone dipropionate. Therefore, clotrimazole and betamethasone dipropionate should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus.
Drugs containing corticosteroids should not be used extensively on pregnant patients in large amounts or for prolonged periods of time.
Nursing Mothers:
Since it is not known whether the components of clotrimazole and betamethasone dipropionate are excreted in human milk, caution should be exercised when this product is administered to a nursing woman.

**Precautions:**
General: Systemic absorption of topical corticosteroids has produced reversible hypothalamicpituitary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria in some patients. 3 Systemic absorption of topical corticosteroid agents will be increased with the use of more potent corticosteroid agents, with prolonged usage or if extensive body surface areas are treated. Therefore, patients receiving large doses of potent topical corticosteroids, applied to a large surface area should be evaluated periodically for evidence of HPA axis suppression. If HPA axis suppression occurs, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute with a less potent corticosteroid agent. Recovery of HPA axis function is generally prompt and complete upon discontinuation of the drug. Infrequently, signs and symptoms of steroid withdrawal may occur, requiring supplemental systemic corticotherapy. If irritation or hypersensitivity develops with the use of clotrimazole and betamethasone dipropionate, treatment should be discontinued and appropriate therapy instituted. Suitable precautions should be taken in using topical corticosteroids in patients with stasis dermatitis and other skin diseases with impaired circulation. Prolonged use of corticosteroid preparations may produce striae or atrophy of the skin or subcutaneous tissue. If this occurs, treatment should be discontinued. Patients should be advised to inform subsequent physicians of the prior use of corticosteroids. Paediatric use: Safety and effectiveness in children below the age of 12 have not been established with clotrimazole and betamethasone dipropionate. 4 The use of clotrimazole and betamethasone dipropionate in diaper dermatitis is not recommended. Paediatric patients may demonstrate greater susceptibility to topical corticosteroid induced HPA axis suppression and Cushing's syndrome than mature patients because of greater absorption due to a larger skin surface area to body weight ratio. Hypothalamic-pituitary-adrenal (HPA) axis suppression, Cushing's syndrome,

and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include linear growth retardation, delayed weight gain, low plasma cortisol levels, and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema. Administration of topical dermatologics containing a corticosteroid to children should be limited to the least amount compatible with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere with the growth and development of children. Laboratory tests If there is a lack of response to clotrimazole and betamethasone dipropionate, appropriate microbiological studies should be repeated to confirm the diagnosis and rule out other pathogens before instituting another course of antimycotic therapy. The following tests may be helpful in evaluating HPA axis suppression due to the corticosteroid component: Urinary free cortisol test ACTH stimulation test

**4.5 Interaction with other medicinal products and other forms of Interactions**

Hypersensitivity to any of the ingredients.

**4.6 Fertility, Pregnancy and lactation:**

Not Available.

**4.7 Effects on ability to drive and use Machines:**

Not Available.

**4.8 Side effects:**

At recommended dose, Cuticor Cream is generally well tolerated, but prolonged use may result in systemic effects.

**Reporting of suspected adverse reactions**

Reporting suspected adverse reactions after authorization of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are requested to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org'

**4.9 Overdosage**

No specific antidote is available and treatment should be symptomatic. Betamethasone dipropionate: Excessive or prolonged use of topical corticosteroids can suppress pituitaryadrenal function, resulting in secondary adrenal insufficiency, and produce manifestations of hypercorticism, including Cushing's disease. Clotrimazole: Overdosage by topical clotrimazole administration is highly improbable, since application of C14 labelled clotrimazole to intact or diseased skin under occlusive dressing for 6 hours did not yield measurable quantities (lower detection limit 0.001 6 µg/mL) of radioactive material in the sera of human subjects. Treatment: Appropriate symptomatic treatment of corticosteroid overdosage is indicated. Acute hypercorticoid symptoms are usually reversible. Treat electrolyte imbalance, if necessary. In cases of chronic toxicity, slow withdrawal of corticosteroids is advised.

## 5. Pharmacological Properties:

### 5.1 Pharmacodynamic Properties:

**Betamethasone Dipropionate**

Betamethasone Dipropionate is a topical corticosteroid having anti-inflammatory, antipruritic and vasoconstrictive action relleving inflammation & itching in skin.

**Clotrimazole**

Clotrimazole is a broad-spectrum antifungal agent available for topical use. Clotrimazole is indicated for the treatment of fungal infections caused by dermatophytes and Candida species.

**Gentamicin Sulphate**

Gentamicin is effective against a wide range of bacilli. Gentamicin shows bactericidal effect.

### 5.2 Pharmacokinetic Properties

**Betamethasone Dipropionate:**

Betamethasone dipropionate, as is characteris c of a cor costeroid, is absorbed through the skin, becomes highly but reversibly bound to plasma proteins, is metabolized at both hepa c and extrahepa c sites to yield mostly inac ve substances and is almost completely excreted within 72 hours. In rats and mice with intact skin, only about 10% of the applied dose of betamethasone dipropionate is absorbed. In skin with the stratum corneum removed, betamethasone is about 90% absorbed when applied cutaneously. The absorbed 11 por on of the steroids is distributed rapidly and found in all organs within 24

hours of administra on. By 48 hours, nearly 90% of the ini al dose was excreted with the remaining por on found in organs of the diges ve tract and kidneys. In rodents, betamethasone dipropionate or its metabolites were excreted predominantly in the faces. The high levels found in the faces indicates that betamethasone dipropionate is metabolized by the liver and excreted in the bile. The two major metabolites of betamethasone dipropionate were shown to be betamethasone 17- propionate and 6 beta 17-propionate and 6 betahydroxybetamethasone 17-propionate.

**Clotrimazole:**

The percutaneous absorption of clotrimazole was examined in humans with radiolabelled clotrimazole (1% cream). The results demonstrated that the highest concentration of clotrimazole remained in the epidermis, particularly the stratum corneum. Very low subcutaneous levels of the drug were detected, and 48 hours after application, serum concentrations were below the detection level of the assay (0.001 mg/L). Urine concentration of the drug was consistently below 0.5% of the radioactivity applied to the skin. Negligible systemic absorption of the drug after intravaginal insertion of one (1) 100 mg tablet was found. The average serum level 24 hours after insertion was approximately 0.03 mg/L. When given orally, however, clotrimazole is rapidly and nearly completely absorbed and distributed throughout the body within hours. The highest concentrations of the drug were found in the liver, adipose tissue and skin. In the rat, the clotrimazole absorbed is eliminated predominantly (more than 90%) in the faces within 48 hours. In man, nearly 25% of the drug is excreted in the urine with the rest excreted in the faces by six (6) days.

**Gentamicin Sulphate:**

**Absorption**

Parenteral (IM, SC and IV):

Less than 1% of a dose of gentamicin is absorbed following oral or rectal administration; it is well absorbed after subcutaneous and intramuscular injection. Serum levels after intramuscular administration are slightly lower than after intravenous administration. After intramuscular administration, peak plasma concentrations are reached in 30 to 90 minutes. A dose of 1 mg/kg produces average peak plasma concentration of about 4 µg/ml although there may be considerable inter-individual variation and higher concentrations in patients with renal impairment (Reynolds, 1982). In critically ill patients (especially with shock) the absorption from intramuscular sites is poor.

Distribution:

Gentamicin is not significantly protein bound. Peak serum levels are observed 30 to 60 minutes after an intramuscular dose and immediately after an intravenous dose.

The volume of distribution is approximately 25% of lean body weight and equal to extracellular fluid volume.

The concentration of gentamicin in secretions and most tissues is low. High concentrations are found in renal cortical tissue, endolymph and perilymph of the inner ear. The concentration in bile approaches close to 30% of serum concentration. Penetration into respiratory secretions is poor. Diffusion into pleural and synovial fluid is slow but considerable concentrations may be achieved with repeated dosing.

The concentration in cerebrospinal fluid (CSF) is less than 10% of the concomitant plasma concentration, though in the presence of meningeal inflammation the concentration may reach 20% of plasma levels. In neonates with meningitis, therapeutic concentrations may be reached in CSF with parenteral dosing alone; in adults, intrathecal administration is necessary.

Similarly, penetration to ocular tissue is minimal and periocular injection of gentamicin is necessary in the treatment of bacterial endophthalmitis.

Biological half-life

The elimination half-life in patients with normal renal function is 2 hours. When creatinine clearance is halved the t1/2 in serum doubles; adjustments are therefore necessary in patients with renal failure (Cutler, 1972). The elimination half-life is 20 to 40 times greater in anephric patients than in patients with normal renal function and it is also prolonged in neonates.

Metabolism

Gentamicin is not metabolized. It is excreted by glomerular filtration in an active, unchanged form.

Elimination by route of exposure

Extremely high urinary concentrations may be achieved: after an intravenous dose of 1 mg/kg, the urinary concentration may reach 100 mg/l and, after 2 mg/kg, 300 mg/l. Gentamicin accumulates in renal cortical tissue, from which it is released over two to three weeks after cessation of therapy. Extremely sensitive assay techniques can detect very small quantities of gentamicin in renal cortical tissue for several months after administration (Schentag et al, 1977).

High concentrations of gentamicin are reached in the liver, but it is not excreted in bile. Drug levels are low in biliary obstruction.

**5.3 Preclinical safety Data:** Not Available.

## 6. Pharmaceutical Particulars:

### 6.1 List of Excipients:

| Sr. No. | Material Name | Specification |
|---|---|---|
| **1.** | Clotrimazole | USP |
| **2.** | Gentamicin Sulfate | BP |
| **3.** | Betamethasone Dipropionate | USP |
| **4.** | Cetosteryl Alcohol | BP |
| **5.** | Cetomacrogol Emulsifying Wax (hydol20) | BP |
| **6.** | Light Liquid Paraffin | BP |
| **7.** | White Soft paraffin | BP |
| **8.** | Hard Paraffin Wax | BP |
| **9.** | Propylene Glycol | BP |
| **10.** | Butylated Hydroxy anisole | BP |
| **11.** | Butylated Hydroxy toluene | BP |
| **12.** | Di Sodium Edetate | BP |
| **13.** | Sodium Acid Phosphate | BP |
| **14.** | Sorbic Acid | BP |
| **15.** | Anhydrous Disodium Hydrogen Phosphate | BP |
| **16.** | Lavender"L"P3029 | IH |
| **17.** | Purified Water | BP |

**6.2 Incompatibilities:** Not known.

**6.3 Shelf life:**

24 Months

**6.4 Special precautions for storage:**

Store below 30 °C in dry place. Protect from light.
Keep medicines out of reach of children.

**6.5 Nature and contents of container:**

20 g printed aluminium tube to be packed in printed carton along with pack insert.

**6.6 Special Precaution for Disposal and other handling:**

None.

**7. Marketing Authorization Holder:**

**Signature Healthcare Limited**

The Eco Green Business Center (TILISI)

OFF A 104 NAIROBI-NAKURU HIGHWAY,

Ngecha, Chunga Mali Road

P.O BOX 66172 00800, Nairobi. KENYA

**Phone No:** 00-254-020-2556185/2556225

**Fax :** 00-254-020-2555811

**E-Mail:** info@signaturehealthcareltd.com

**Name and address of Manufacture:**

**(Company) Name: CORAL LABORATORIES LIMITED**

Address : Plot No. 27-28, Pharmacity, Selaqui, Dehradun – 248 011, Uttarakhand. India.

Email : exports@corallab.com

Website : www.corallab.com

**8. Marketing Authorization Numbers**

H2022/CTD9117/20302

**9. Date of first Registration /renewal of the Registration:**

Date of First Registration: 31 OCTOBER 2022

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

07.07.2026