1.3 Product Information

1.3.1 Summary of Product Characteristics (SmPC)

1. Name of the medicinal product

1.1 (Invented) Name of the medicinal product
KESCEF (BETAMETHASONE DIPROPIONATE, GENTAMICIN SULPHATE & CLOTRIMAZOLE CREAM)

1.2 Strength

Betamethasone Dipropionate BP	0.50 mg
Clotrimazole BP	10 mg
Gentamicin sulphate BP	
Eq. To Gentamicin Base	1 mg
Cream Base	Q.S

1.3 Pharmaceutical Form
Cream

2. Qualitative and Quantitative Formula

Batch Size: 200 Kg (6666 Tubes)

Batch Size: 200 kg (6666 tubes)

Sr No.	Ingredients	Label Claim	Qty/ Tube (mg)	Qty/ Batch (Kg)	Overages (%)	Functions
1	Betamethasone Dipropionate B.P.	0.50 mg	15.75	0.105	5%	Anti-inflammatory
2.	Gentamicin Sulphate Eq. to Gentamicin BP	1 mg	36	0.240	20%	Anti-bacterial
3.	Clotrimazole BP	10 mg	315	2.100	5%	Antifungal
4.	White Soft Paraffin BP	-	450.0	30.000	-	Emollient
5.	Cetostearyl Alcohol BP	-	2160.0	14.400	-	Viscosity increasing agent
6.	Cetomacrogol –1000 BP	-	540.00	3.600	-	Ointment base
7.	Light Liquid Paraffin BP	-	1050.00	7.000	-	Lubricant
8.	Chlorocresol BP	-	30.00	0.200	-	Preservative
9.	Propylene Glycol BP	-	1500.00	10.000	-	Vehicles
10.	Purified Water BP***	-	Q.S. to 30.0 gm.	Q.S. to 200 kg	-	Vehicle

3. Pharmaceutical form
White coloured smooth cream.

4. Clinical particulars:

4.1 Therapeutic Indication:

Kescef is indicated for the treatment of corticosteroid-responsive dermatoses when complicated by infections caused by bacteria (sensitive to gentamicin) and fungi (sensitive to clotrimazole) or when the possibility of such infections is suspected. the cream is suitable for the use of oozing eczema.

4.2 Posology and method of administration:

Dose: A thin film of Kescef should be applied to cover completely the affected and surrounding skin areas twice daily, in the morning and at night. For treatment to be effective, Gloactiv dermal Cream should be applied regularly. **Duration of Treatment**: Duration of therapy varies depending upon the extent and location of disease and patient response. However, if clinical improvement is not achieved by three to four weeks, diagnosis should be reviewed.

Method of Administration: FOR DERMATOLOGIC USE ONLY

4.3 Contraindications

Kescef is contraindicated in those patients with a history of sensitivity reactions to any of its components

4.4 Special warnings and precautions for use:

If irritation or sensitization develops with the use of Cream or Ointment, treatment should be discontinued and appropriate therapy instituted. Any of the side effects that are reported following systemic use of corticosteroids, including adrenal suppression, may also occur with topical corticosteroids, especially in infants and children. Cross-allergenicity among aminoglycosides has been demonstrated. Systemic absorption of topical corticosteroids or gentamicin will be increased if extensive body surface areas are treated or if occlusive dressings are used, especially over prolonged time periods or in the presence of dermal disruption. Application of gentamicin to open wounds or damaged skin should be avoided. In these cases, the undesirable effects which occur following systemic use of gentamicin may potentially occur. Cautious use is recommended under these conditions, particularly in infants and children. Prolonged use of topical antibiotics occasionally may result in overgrowth of nonsusceptible microorganisms. If this occurs or if irritation, sensitization or superinfection 3 of 6 develops, treatment with Cream should be therapy indiscontinued and Cream is not for ophthalmic use. Pediatric Use: Pediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced hypothalamic-pituitary-adrenal (HPA) axis suppression and to exogenous corticosteroid effects than mature patients because of greater absorption due to a large skin surface area to body weight ratio. HPA axis suppression, Cushing's syndrome, linear growth retardation, delayed weight gain, and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include low plasma cortisol levels and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include a bulging fontanelle, headaches and bilateral papilledema.

4.5 Interaction with other medicinal products and other forms of interaction

N/A

4.6 Fertility, Pregnancy and lactation

Since safety of topical corticosteroid use in pregnant women has not been established, drugs of this class should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Drugs of this class should not be used extensively in large amounts or for prolonged periods of time in pregnant patients. Since it is not known whether topical administration of corticosteroids can result in sufficient systemic absorption to produce detectable quantities in breast milk, a decision should be made to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

4.7 Effects on ability to drive and use machines:

If you experience drowsiness, dizziness, hypotension or a headache as side-effects when using cream medicine then it may not be safe to drive a vehicle or operate heavy machinery. One should not drive a vehicle if using the medicine makes you drowsy, dizzy or lowers your blood-pressure extensively.

4.8 Overdose:

Symptoms: Excessive or prolonged use of topical corticosteroids can suppress pituitary-adrenal function, resulting in secondary adrenal insufficiency and produce manifestations of hypercorticism, including Cushing's disease. Since application of 14C labeled clotrimazole+ to intact or diseased skin under occlusive dressing for six hours did not yield measurable quantities (lower detection limit 0.001 mcg/ml) of radioactive material in the sera of human subjects, overdosage by topical clotrimazole administration is highly improbable. A single overdose of gentamicin would not be expected to produce symptoms. Excessive or prolonged use of topical gentamicin may lead to overgrowth of lesions by non-susceptible microorganisms.

Treatment: Appropriate symptomatic treatment is indicated. Acute hypercorticoid symptoms are usually reversible. Treat electrolyte imbalance, if necessary. In case of chronic toxicity, slow withdrawal of corticosteroids is advised. If overgrowth by non-susceptible microorganisms occurs, stop treatment with Gloctiv dermal Cream and institute appropriate therapy. + Six hours after the application of radioactive clotrimazole 1% cream or 1% solution onto intact or acutely inflamed skin, the concentration of clotrimazole varied from 100 mcg/cm3 in the stratum corneum to 0.5 to 1 mcg/cm3 in the stratum reticulare, and 0.1 mcg/cm3 in the subcutis. No measurable amount of radioactivity (0.001 mcg/ml) was found in the serum within 48 hours after application under occlusive dressing of 0.5 ml of the solution or 0.8 g of the cream..

5. Pharmacological properties

5.1 Pharmacotherapeutic Group

Topical corticosteroid and anti-infectives in combination

5.2 Pharmacodynamic properties

Mechanism of Action: Cream combines the sustained anti-inflammatory, antipruritic and vasoconstrictive actions of betamethasone dipropionate with the broad

spectrum antifungal activity of clotrimazole and the wide-spectrum bactericidal antibiotic activity of gentamicin sulfate. Clotrimazole appears to act on the fungal cell membrane, causing leakage of cell contents. Gentamicin provides highly effective topical treatment in primary and secondary bacterial infections of the skin.
Pharmacodynamic Effects (e.g. Subsections: Resistance, In Vitro Susceptibility Data)
Bacteria susceptible to gentamicin include sensitive strains of Staphylococcus aureus (coagulase positive, coagulase negative and some penicillinase-producing strains) and the gram-negative bacteria: Pseudomonas aeruginosa, Aerobacter aerogenes, Escherichia coli, Proteus vulgaris and Klebsiella pneumoniae.

6. Pharmaceutical particulars

6.1 List of Excipients

Sr.No.	Excipients	Specification
1	White Soft Paraffin BP	BP
2	Cetostearyl Alcohol BP	BP
3	Cetomacrogol –1000 BP	BP
4	Light Liquid Paraffin BP	BP
5	Chlorocresol BP	BP
6	Propylene Glycol BP	BP
7	Purified Water BP	BP

6.2 Incompatibilities

Not Applicable

6.3 Shelf life

24 months from the date of manufacturing.

6.4 Special precautions for storage

Keep below 30°C. Protect from light. Keep medicines out of the reach ofchildren.

6.5 Nature and contents of container

30 gm Cream Tube is packed in printed carton along with package insert.

6.6 Special precautions for disposal

No special requirements.

7. REGISTRANT

ANTILA LIFESCIENCES PVT. LTD.
Mfg. At: Near Sabar Daily, Talod Road,
P.O Hajipur, Tal- Himatnagar, City- Hajipur-383006,
Dist- Sabarkantha, Gujarat, India.

8. DATE OF REVISION OF THE TEXT

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9. NAME AND ADDRESS OF MANUFACTURER

ANTILA LIFESCIENCES PVT. LTD.

Mfg. At: Near Sabar Daily, Talod Road,
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