1. NAME OF THE MEDICINAL PRODUCT

Trade Name: ZUBACT

Generic Name: Betamethasone Dipropionate, Gentamicin Sulfate, Tolnaftate, Iodochlorhydroxyquinoline Cream

Composition:

Each gram contains:

- Betamethasone Dipropionate USP (0.643 mg)
- Iodochlorhydroxyquinoline (In House) (10.0 mg)
- Tolnaftate USP (10.0 mg)
- Gentamicin Sulfate BP equivalent to Gentamicin Base (1.0 mg)
- Chlorocresol BP (1 mg)
- Cream Base (- QS)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Sr. No.	Ingredients	Specifi-cation	Label Claim / gm (in % w/w)	Overages (%)	Qty. / Tube (30 gm) contains (in kg)	Reason for inclusion
1.	Betamethasone Dipropionate	USP	0.643 mg	5%	0.405	Active Pharmaceutical Ingredient
2.	Iodochlorhydroxyquinoline	IHS	10 mg	5%	6.30	Active Pharmaceutical Ingredient
3.	Gentamicin Sulfate eq to gentamicin	BP	1.0 mg	5%	0.960	Active Pharmaceutical Ingredient
4.	Tolnaftate	USP	10 mg	5%	6.30	Active Pharmaceutical Ingredient
5.	Chlorocresol	BP	--	--	0.60	Active Pharmaceutical Ingredient
6.	Potassium dihydrogen phosphate	BP	--	--	0.48	Buffering agent
7.	Disodium hydrogen ortho phosphate	BP	--	--	0.75	Buffering agent
8.	Light liquid paraffin	BP	--	--	36.00	Therapeutic agent
9.	White soft paraffin	BP	--	--	90.00	Emollient
10.	Propylene glycol	BP	--	--	60.0	Disinfectant
11.	Disodium EDTA	BP	--	--	0.60	Chelating agent
12.	Cetosteryl alcohol	BP	--	--	46.8	emulsifying agent
13.	Cetomacrogol 1000	BP	--	--	7.20	Emulsifying agent
14.	Sodium metabisulphite	BP	--	--	0.60	Antioxidant
15.	Purified Water	BP	--	--	Q.S	Solvent

3. PHARMACEUTICAL FORM

Cream

4. Clinical particulars

4.1 Therapeutic indications

ZUBACT is indicated for the treatment of following: Mixed bacterial and fungal infections, Tinea Infections of the skin (Ringworm), Otitis externa, Seborrhoeic dermatitis, Contact dermatitis, Eczemas, Psoriasis, Athlete's foot, Anal & vulval pruritis.

4.2 Posology and method of administration

Apply 2-3 times of Epiderm Cream a day to the affected area or as directed by physician.

4.3 Contraindications

ZUBACT is contraindicated in patients who are hypersensitive to any of the component of the drug. It is also contraindicated in the treatment of herpes simplex, vaccina or varicella.

4.4 Special warnings and precautions for use

Paediatric Use: HPA axis suppression, Cushing's syndrome and intracranial hypertension have been Reported in paediatric patients receiving topical corticosteroids.

4.5 Interaction with other medicinal products and other forms of interaction

None has been reported on local application. Avoid using other topical medications.

4.6 Pregnancy and Lactation

ZUBACT is not safe in pregnancy. Physician should be consulted before initiating therapy with Epiderm Cream for nursing mothers.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

ZUBACT is generally well tolerated. Some of the rarely reported side effects are burning sensation, itching, irritation, dryness, folliculitis, acneform eruptions, hypopigmentation, maceration of the skin, secondary infection, skin atrophy etc.

4.9 Overdose

Excessive prolonged use of topical corticosteroids can suppress pituitary-adrenal functions resulting in Secondary adrenal insufficiency which is usually reversible. In such cases appropriate symptomatic Treatment is indicated. If HPA axis suppression is noted, an attempt should be made to withdraw the drug, reduce the frequency of application, or to substitute a less potent steroid.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

Pharmacological category: Epiderm Cream is a combination of anti-fungal, anti-bacterial & antiinflammatory drugs, which provide synergetic action in treatment of mix bacterial & fungal infections. Pharmacological action: Corticosteroids are thought to act by the induction of phospholipase A2 Inhibitory proteins, collectively called lipocortins. It is postulated that these proteins control the Biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes. Gentamicin is an aminoglycoside that binds to 30s and 50s ribosomal subunits of susceptible bacteria disrupting protein synthesis, thus rendering the bacterial cell membrane defective. Tolnaftate is an antifungal which inhibits growth of dermatophytes. Iodochlorhydroxyquinoline has antibacterial and antifungal activity.

5.2 Pharmacokinetic properties

Epiderm Cream: Absorption: Percutaneous absorption
Elimination: Via urine.

5.3 Preclinical safety data

None

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

The active ingredients Betamethasone Dipropionate USP, Gentamicin Sulfate BP, Tolnaftate USP, Iodochlorhydroxyquinoline IHS. The other ingredients are Chlorocresol BP, Potassium dihydrogen phosphate BP, Disodium hydrogen ortho phosphate BP, Light liquid paraffin BP, White soft paraffin BP, Propylene glycol BP, Disodium EDTA BP, Cetosteryl alcohol BP, Cetomacrogol 1000 BP, Sodium metabisulphite BP, Purified Water BP.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store below 25°C. Protected from light. Do not allow to freeze.
Keep all medicines out of reach of children.

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

Primary packing: 30 gm of Cream is filled in a Lamitube.
Secondary packing: Such 1 tube is packed an inner carton along with leaflet.
Tertiary packing: 12 Inner cartons are packed in an outer carton. Individually shrink outer carton. Such 30 Shrinks are packed in a 5 Ply Shipper sealed with BOPP tape & strap with strapping roll.

6.6 Special precautions for disposal <and other handling>

No special requirements.

7. <APPLICANT/MANUFACTURER>

KGN PHARMACEUTICALS PVT. LTD.

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Maharashtra, India