KGN® Keep Healthy...	KGN PHARMACEUTICALS PVT. LTD.
	KLEBACT
	Clotrimazole, Betamethasone Dipropionate and Neomycin Sulfate Cream

SUMMARY OF PRODUCT CHARACTERISTICS (SMPC)

1. Name of the medicinal product

Trade Name: KLEBACT
Generic Name: Clotrimazole, Betamethasone Dipropionate and Neomycin Sulfate Cream

Composition:
- Clotrimazole USP (1.0 % W/W)
- Betamethasone Dipropionate USP Eq. to Betamethasone (0.05 % W/W)
- Neomycin Sulfate USP (0.5 % W/W)
- Cream Base (- QS)
- Chlorocresol USP / NF (0.1 % W/W)

2. Qualitative and quantitative composition

Sr. No.	Ingredients	Specifi-cation	Label Claim / gm (in % w/w)	Over ages (%)	Qty. / Tube (30 gm) contains (in kg)	Reason for inclusion
1.	Clotrimazole	USP	1.0% w/w	5 %	6.300	Active Pharmaceutical Ingredient
2.	Betamethasone Dipropionate eq. to Betamethasone	USP	0.05% w/w	--	0.405	Active Pharmaceutical Ingredient
3.	Neomycin Sulfate	USP	0.5% w/w	--	4.410	Active Pharmaceutical Ingredient
4.	Chlorocresol	USP	0.1% w/w	--	0.600	Preservative
5.	Potassium Dihydrogen Ortho Phosphate	BP	--	--	0.480	Emulsifying Agent
6.	Disodium Hydrogen Ortho Phosphate	BP	--	--	0.750	Preservative
7.	Light Liquid Paraffin	BP	--	--	36.000	Emollient
8.	Propylene Glycol	BP	--	--	45.000	Solvent
9.	White Soft Paraffin	BP	--	--	90.000	Moisturiser
10.	Cetostearyl Alcohol	BP	--	--	46.800	Opacifying Agent
11.	Ceto Macrogol 1000	BP	--	--	7.200	Solubilizer & Emulsifying Agent
12.	Purified Water	BP	--	--	Q.S.	Vehicle

3. Pharmaceutical form
Oral Solid Dosage Form

4. Clinical particulars
4.1 Therapeutic indications
KLEBACT is indicated for topical use in the treatment of a wide range of eczemas and other inflammatory and allergic infections of the skin caused by various bacteria / fungi. This condition includes contact dermatitis, follicular dermatitis, impetigo, intertrigo, eczematoid dermatitis, non-specific pruritus etc.

4.2 Posology and method of administration
After cleaning the affected area, a sufficient quantity of **KLEBACT** should be applied to the affected area to form a thin even layer, two or three times daily. This treatment should be continued for several days after the disappearance of symptoms.

4.3 Contraindications
KLEBACT is contraindicated:
- if you are allergic to betamethasone dipropionate, clotrimazole and neomycin sulfate or any of the other ingredients of this medicine.
- if your skin becomes irritated, or you develop an allergic reaction.
- do not use on any other skin infections as it could make them worse, especially rosacea (a skin condition affecting the face), acne, dermatitis (skin inflammation) around the mouth, nappy rash or other skin infections.

4.4 Special warnings and precautions for use
If you have psoriasis, your doctor may want to review your treatment regularly. Contact your doctor if your psoriasis gets worse or you get raised bumps filled with pus under your skin.
Contact your doctor immediately if you, or your child, experience blurred vision or other visual disturbances.
Side effects that may happen with inhaled or oral corticosteroids may also occur with corticosteroids used on the skin, especially in infants and children.
If you use more than the correct amount of cream and/or use it for longer than is recommended, it can affect the levels of certain hormones in the body, particularly in infants and children.
In adults the changes in hormone levels may lead rarely to puffiness or rounding of the face, weakness, tiredness, and dizziness when standing or sitting down.
Children
Do not use this medicine on children under 12 years of age unless advised by your doctor.
If you use more than the correct amount of cream and/or use it for longer than is recommended, it can affect your child's hormones. Rarely this may lead to:
• Delayed growth and development
• A moon face or rounding of the face
• A build-up of pressure around the brain which can produce
- a bulging of the fontanelle (the soft spot in the top of the skull) in infants
- a constant thumping headache
- blurred vision or other visual disturbances.

4.5 Interaction with other medicinal products and other forms of interaction
Following significant systemic absorption, Neomycin Sulfate can intensify and prolong the respiratory depressant effects of neuromuscular blocking agents.
Laboratory tests have suggested that, when used together, this product may cause damage to latex contraceptives. Consequently, the effectiveness of such contraceptives may be reduced. Patients should be advised to use alternative precautions for at least five days after using this product.

4.6 Pregnancy and lactation
There is little information to demonstrate the possible effect of topically applied Neomycin in pregnancy and lactation. However, Neomycin present in maternal blood can cross the placenta and may give rise to a theoretical risk of foetal toxicity, thus use of this medicinal product is not recommended in pregnancy or lactation.
Pregnancy:
There is a limited amount of data from the use of clotrimazole in pregnant women. Animal studies with clotrimazole have shown reproductive toxicity at high oral doses. At the low systemic exposures of clotrimazole following topical treatment, harmful effects with respect to reproductive toxicity are not predicted. Clotrimazole can be used during pregnancy but only under the supervision of a physician or midwife.

Lactation:
Available pharmacodynamic/toxicological data in animals have shown excretion of clotrimazole/metabolites in milk after intravenous administration. A risk to the suckling child cannot be excluded. A decision must be made whether to discontinue breastfeeding or to discontinue/abstain from clotrimazole therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.

Fertility:
No human studies of the effects of clotrimazole on fertility have been performed; however, animal studies have not demonstrated any effects of the drug on fertility.

4.7 Effects on ability to drive and use machines
Not applicable.

4.8 Undesirable effects
Skin atrophy or striae may occur following long-term treatment with preparation containing corticosteroids.

4.9 Overdose
Acute overdosage with topical application of **KLEBACT** 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 **KLEBACT**. Signs of toxicology appearing after such accidental ingestion should be treated symptomatically.

5. Pharmacological properties

5.1 Pharmacodynamic properties

KLEBACT contains the dipropionate ester of betamethasone, a glucocorticoid exhibiting the general properties of corticosteroids, clotrimazole which is an imidazole antifungal agent and Neomycin Sulfate which is aminoglycoside antibiotics.

Topical corticosteroids are effective in the treatment of a range of dermatoses because of their anti-inflammatory anti-pruritic and vasoconstrictive actions.

Clotrimazole is a broad-spectrum antifungal agent with activity against Trichomones, Staphylococci and Bacteroides.

Neomycin mediates its bactericidal action by inhibiting bacterial protein synthesis, thereby suppressing the growth and survival of susceptible bacteria.

5.2 Pharmacokinetic properties

Clotrimazole

Clotrimazole penetrates the epidermis after topical administration but there is little, if any, systemic absorption.

Betamethasone Dipropionate

The absorption and potency of any topical corticosteroid including betamethasone depends on the vehicle in which the steroid is delivered. The metabolism of betamethasone yields 6 metabolites. The metabolic processes include 6β hydroxylation, 11β-hydroxyl oxidation, and reduction of the C-20 carbonyl group followed by removal of the side chain. Corticosteroids are eliminated predominantly in the urine.

Neomycin Sulfate

The small absorbed fraction is rapidly distributed in the tissues and excreted by the kidneys. The unabsorbed portion of neomycin (97%) is primarily excreted unchanged in feces. The amount of systemically absorbed neomycin transferred to the tissues increases cumulatively with repeated dosing with the kidneys as the primary excretory path. With repeated dosing, progressive accumulation also occurs in the inner ear. Release of tissue-bound neomycin occurs slowly over a period of several weeks after dosing has been discontinued. Protein binding is low (0—30%).

6. Preclinical safety data

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

7. Pharmaceutical particulars

7.1 List of excipients

Chlorocresol USP, Potassium Dihydrogen Ortho Phosphate BP, Disodium Hydrogen Ortho Phosphate BP, Light Liquid Paraffin BP, Propylene Glycol BP, White Soft Paraffin BP, Cetostearyl Alcohol BP & Ceto Macrogol 1000 BP.

7.2 Incompatibilities

Not applicable.

7.3 Shelf life
3 years.

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

7.5 Nature and contents of container
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.

7.6 Special precautions for disposal and other handling
No special requirements.

8. Marketing authorisation holder
KGN PHARMACEUTICALS PVT. LTD.
F-3/1, MIDC Tarapur, Boisar, Dist.: Palghar, 401506,
Maharashtra, India

9. Marketing authorisation number(s)
New registration

10. Date of first authorisation/renewal of the authorisation
New registration

11. Date of revision of the text
New registration