1. NAME OF THE MEDICINAL PRODUCT:

SMOTBACT CREAM

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each gram contains:
Gentamicin Sulfate BP
Eq. Gentamicin base……. 1 mg
Clotrimazole BP……10 mg
Betamethasone Dipropionate USP
Eq. to Betamethasone…….....…….…..0.5 mg
Cream Base…….……..…. Q.S.

3. PHARMACEUTICAL FORM: TOPICAL CREAM

A white to off-white smooth cream.

4. CLINICAL PARTICULARS:

4.1 Therapeutic indications:

SMOTBACT CREAM is indicated for the topical treatment of Antifungal, Antibacterial & Anti-inflammatory.
SMOTBACT CREAM is indicated for the treatment of the following conditions where secondary bacterial infection is present, suspected, or likely to occur
Adults and children (aged 2 years and over): Eczema including atopic and discoid eczemas; prurigo nodularis; psoriasis (excluding widespread plaque psoriasis); neurodermatoses including lichen simplex and lichen planus; seborrhoeic dermatitis; contact sensitivity reactions; insect bite reactions and anal and genital intertrigo.

4.2 Posology and method of administration

Direction: A thin film of cream should be applied to cover completely the affected area 2 – 3 times daily with gentle rub.

Route: For external application only.

4.3 Contraindications

SMOTBACT CREAM is contraindicated in patients with hypersensitivity or allergy to any of the excipients of the product.
SMOTBACT CREAM is contraindicated in patients with conditions such as rosacea, acne vulgaris, perioral dermatitis, perianal and genital pruritus, primary cutaneous viral infections, otitis external and hypersensitivity to any component of the preparation.

4.4 Special warnings and precautions for use

SMOTBACT CREAM should not be used with occlusive dressings.

The precautions in patients with broken skin, i.e. Local & Systemic toxicity is common especially following long continued use on large areas of damaged skin and in flexure. If used on the face courses should be limited to 5 days.
Long term continuous therapy should be avoided, particularly in infants and children where adrenal suppression may occur even without occlusion.
If irritation or sensitisation develops, treatment should be discontinued, and appropriate remedial therapy instituted.
In the presence of bacterial or viral infection, an appropriate antibacterial or antiviral agent should be administered concurrently. If response does not occur promptly **SMOTBACT CREAM** should be discontinued until the infection has been controlled adequately.
Systemic absorption of topical corticosteroids will be increased if extensive body surface areas or skin folds are treated. Suitable precautions should be taken under these conditions or when long term use is anticipated, particularly in infants and children.
Any of the side effects that are reported following systemic use of corticosteroids, including adrenal suppression, manifestation of Cushing's syndrome, hyperglycemia, and glycosuria may also occur with topical steroids, especially in infants and children.
Hypothalamic-pituitary adrenal axis suppression. Cushing's syndrome and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestation of adrenal suppression in children include linear growth retardation, delayed weight gain, low plasma cortisol levels, and absence of response to ACTH stimulation Manifestation of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilla-edema. The safety and effectiveness of **SMOTBACT CREAM** in children below the age of 12 has not been established.
SMOTBACT CREAM is not intended for ophthalmic use.
Smotbact Cream contains Propylene glycol may cause skin irritation. Chlorocresol may cause allergic reactions & Cetostearyl Alcohol may cause local skin reactions (e.g. Contact dermatitis.) Benzyl Alcohol which may cause allergic reactions or mild local irritation.

4.5 Interaction with other medicinal products and other forms of interaction
None reported.

4.6 Fertility, pregnancy and lactation
Studies in animals have shown a teratogenic effect. To date no such effects have been reported in human beings during pregnancy or lactation. However, this product should not be used in pregnancy or lactation unless considered essential by the physician.
It is not known whether the components of **SMOTBACT CREAM** are excreted in human milk and therefore caution should be exercised when treating nursing mothers.

4.7 Effects on ability to drive and use machines
The medicinal product has no influence on the ability to drive or operate machinery

4.8 Undesirable effects
Adverse reactions reported for **SMOTBACT CREAM** include: burning and stinging, maculopapular rash, oedema, paraesthesia and secondary infection.
Reported reactions to clotrimazole include erythema, stinging, blistering, peeling, oedema, pruritus, urticaria and general irritation of the skin.

Reactions to betamethasone Dipropionate include: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hyperpigmentation, hypopigmentation perioral dermatitis, and allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae, miliaria, capillary fragility (ecchymoses) and sensitisation. In children receiving topical corticosteroids, Hypothalamic-pituitary adrenal (HPA) axis suppression, Cushing's syndrome and intracranial hypertension have been reported.
Delayed type hypersensitivity reactions have been reported during use of Gentamicin; sensitization has been reported following prolonged use. Ototoxicity and nephrotoxicity have been reported when applied to large surfaces or damaged skin.

4.9 Overdose
Acute overdosage with topical application of **SMOTBACT CREAM** (**Betamethasone, Gentamicin & Clotrimazole Cream)** 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 **SMOTBACT CREAM** (**Betamethasone, Gentamicin & Clotrimazole Cream)** Accidental ingestion should be treated symptomatically.

5. Pharmacological properties
5.1 Pharmacodynamic properties
ATC Code: D07AC01, D01AC20 & D06AX04
Pharmacotherapeutic group: Antifungal, Antibacterial, Anti inflammatory
Betamethasone Dipropionate is one of the most potent topical corticosteroids available and rapidly controls symptoms such as itching, redness and scaling. Many times, the inflammatory skin disorders which respond to topical corticosteroids are superadded with bacterial and / or fungal infections of the skin. In these conditions, treatment with anti-inflammatory agents alone is not sufficient and a proper antibiotic has to be added in the regimen.
Clotrimazole is a broad spectrum synthetic antifungal agent which has fungicidal action against all the fungi responsible for superfacial fungal infections of skin. Gentamicin sulfate is Gram negative bacteria & Streptococus aureus.

5.2 Pharmacokinetic properties
Smothact Cream is intended for treatment of skin conditions and is applied topically.
1.Betamethasone Dipropionate:
Topical:-Absorption: It is absorbed in to the systemic circulation and the amount is depending on the potency, amount applied and the nature of the skin at the site of application. Absorption increases at the site of skin damage, inflammation or occlusion.
2. Gentamicin Sulfate:
Gentamicin can be absorbed through inflamed skin. Once absorbed, it is rapidly excreted unchanged through the kidneys. The half-life is approximately 2 to 3 hours.
3. Clotrimazole: Absorption is minimal after topical administration.

5.3 Preclinical safety data
Not applicable.

6. Pharmaceutical particulars

6.1 List of excipients

Cetomacrogol 1000
Cetostearyl Alcohol
White Soft Paraffin
Sodium Acid Phosphate
Disodium Hydrogen Phosphate
Chlorocresol
Light Liquid Paraffin
Propylene Glycol
Benzyl Alcohol
Purified Water

6.2 Incompatibilities

None known.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store at temperature not exceeding 30°C; do not freeze.

6.5 Nature and contents of container

The cream is filled into lami tubes with white colour stand-up caps and enclosed in an outer carton. Pack sizes available are 30g.

6.6 Special precautions for disposal and other handling

Not applicable.

ADMINISTRATIVE DATA:

7. Marketing authorisation holder
Kremoint Pharma Pvt. Ltd.,
B-8 Additional MIDC, Ambernath
Ambernath (E). Thane 421506

8. Marketing authorisation number(s):
MH/DRUGS/146

9. Date of first authorisation/renewal of the authorisation
---

10. Date of revision of the text:
