1. **NAME OF THE DRUG PRODUCT**

Brand Name: -----

Generic Name: Betamethasone Dipropionate, Neomycin Sulfate & Clotrimazole Cream

Strength:

Betamethasone Dipropionate USP
Eq. to Betamethasone…….0.05%w/w
Clotrimazole USP……...1.0% w/w
Neomycin Sulfate USP……...0.5%w/w
Preservative:
Chlorocresol USP…….0.1%w/w
Cream base…….q.s.

Dosage form: Cream for Tropical use.

Rout of administration: Tropical Use

2. **QUALITATIVE AND QUANTITATIVE COMPOSITION**

Label claim:

Betamethasone Dipropionate USP
Eq. to Betamethasone…….0.05%w/w
Clotrimazole USP……...1.0% w/w
Neomycin Sulfate USP……...0.5%w/w
Preservative:
Chlorocresol USP…….0.1%w/w
Cream base…….q.s.

3. **PHARMACEUTICAL FORM**

Cream

A white colour semi solid mass filled in printed Lami tube.

4. **CLINICAL PARTICULARS**

4.1 Therapeutic indications:

Betamethasone Dipropionate, Neomycin Sulphate & Clotrimazole Cream is used to treat fungal and bacterial skin infections. It treats skin inflammation due to allergies or irritants, eczema (inflamed, itchy, cracked and rough skin patches), psoriasis (skin cells multiply rapidly to form bumpy/uneven red patches covered with white scales), insect bites and stings. Bacterial infection occurs when harmful bacteria grow in the body and cause infection. Fungal infection is caused when a fungus invades and affects the tissue on the skin.

4.2 Posology/Dosage and method of administration:

For topical administration.
Apply a thin layer to the affected area 2 - 3 times daily or as directed by a physician.

USE IN SPECIAL POPULATIONS

Fertility, Pregnancy and Lactation
No Data Available for Pregnancy & Lactation

Paediatric Patients
No Data Available for Paediatric Patient.

Geriatric Patients
No overall differences in effectiveness or safety have been observed between the elderly population and younger subjects.

4.3 Contraindication:

Betamethasone Dipropionate, Neomycin Sulphate & Clotrimazole Cream is contraindicated in patients with known allergies to any of the combination's components and in patients with fungal infections (such as ringworm or athlete's foot), viral infections (like herpes or chickenpox), or for treating acne or rosacea.

4.4 Special warnings and precautions for use

If you're allergic to this medicine, don't take it. Seek medical help right away if you have any allergic reactions. Avoid smoking or going near naked flames since Beclomethasone Dipropionate, Neomycin Sulphate & Clotrimazole Cream can catch fire and burn easily. Avoid applying Beclomethasone Dipropionate, Neomycin Sulphate & Clotrimazole Cream on sunburns, lesions, blisters and open wounds. Beclomethasone Dipropionate, Neomycin Sulphate & Clotrimazole Cream is not for oral, ophthalmic (for the eye) or intravaginal use.

4.5 Interaction with other drug products and other forms of interaction

Betamethasone Dipropionate, Neomycin Sulphate & Clotrimazole Cream may interact with respiratory-related medicines (budesonide, formoterol), drugs treating HIV/AIDS (ritonavir, cobicistat), fluid retention drugs (furosemide), antibiotics (bacitracin, polymyxin b) and corticosteroids.

4.6 Fertility, pregnancy and lactation

Pregnancy: Safety of using this medicine during pregnancy has not been evaluated. Topical corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing mothers: It is not known whether topical administration of this medicine is absorbed to produce detectable quantities in breast milk. Use with caution in breast-feeding women.

4.7 Effects on ability to drive and use machines

There have been no studies to investigate the effect of Betamethasone+Clotrimazole+Neomycin on driving performance or the ability to operate machinery. A detrimental effect on such activities would not be anticipated from the adverse reaction profile of topical Betamethasone+Clotrimazole+Neomycin.

4.8 Undesirable effects

Betamethasone Dipropionate, Neomycin Sulphate & Clotrimazole Cream include redness, itching, dryness and a burning sensation at the application site. Most of these side effects do not necessitate medical attention and gradually resolve over time. However, if the side effects persist or worsen, please consult a doctor.

4.9 Overdose

An overdose of this medication could lead to thinning of the skin, changes in skin colour, excessive hair growth, secondary infections, or allergic reactions such as rash, swelling, and difficulty breathing. If you observe any of these symptoms, consult your doctor immediately.

If you forget to apply this medication at the directed time, do so as soon as you remember. However, avoid applying double the amount if it is close to the time for the next application.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Clotrimazole exerts antifungal effects by inhibition of fungal sterol synthesis. It appears to inhibit the enzymatic conversion of 2,4-methylene-dihydrolanosterol to demethylsterol, the precursor to ergosterol which is an essential building block of the cytoplasmic membrane of the fungi. Clotrimazole is a broad spectrum antifungal agent that inhibits the growth of most fungi pathogenic to man, including the Candida and Dermatophytes (Trichophyton, Microsporum, Epidermophyton).

Topical corticosteroids, such as betamethasone dipropionate, are effective in the treatment of corticosteroid-responsive dermatoses primarily because of their anti-inflammatory, antipruritic and vasoconstrictive actions. The mechanism of the anti-inflammatory activity of the topical steroids, in general, is unclear. However, corticosteroids are thought to act by the induction of phospholipaseA2 inhibitory proteins, collectively called lipocortins. It is postulated that these proteins control the biosynthesis of potent mediators of inflammation, such as prostaglandins and leukotrienes, by inhibiting the release of their common precursor, arachidonic acid.

Neomycin acts both on gram-positive bacteria such as Streptococci, Staphylococci and on gram-negative bacteria such as E. coli and Proteus. This antibiotic is used in wide variety of local infections, including infected dermatoses, burns, wounds and/or ulcers. This is incorporated into topical steroid preparations to control secondary infections in inflammatory disorders. Applied topically, this drug is well tolerated, relatively non-irritating, and has a low index of sensitivity.

In cases where local action on infecting bacteria and fungi is required, the anti-inflammatory and antipruritic effects accelerate the improvement of clinical symptoms. In cases where a local anti-inflammatory and antipruritic effect is required, any infection by bacteria and fungal is at the same time eliminated or prevented. The base is a cosmetically acceptable, well tolerated cream (Type O/W) which will not stain the skin.

5.2 Pharmacokinetic properties

Small amount of Clotrimazole (<2-3% of the dose) is absorbed following dermal application. The resulting peak plasma concentrations of the active ingredient are <10mglml and do not lead to noticeable systemic effects or side effects.

Betamethasone dipropionate - The extent of percutaneous absorption of topical corticosteroids is determined by many factors including the vehicle, the integrity of the epidermal barrier, and the use of occlusive dressings. Topical corticosteroids can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin increase percutaneous absorption. Occlusive dressings substantially increase the percutaneous absorption of topical corticosteroids. Corticosteroids are bound to plasma proteins in varying degrees. Corticosteroids are metabolized primarily in the liver and are then excreted by the kidneys. Some of the topical corticosteroids and their metabolites are also excreted into the bile.

Neomycin sulfate is not absorbed following topical application to intact skin; however, the drug is readily absorbed through denuded or abraded areas of skin or skin that has lost the keratin layer as in wounds, burns, or ulcers. Neomycin is rapidly absorbed from the peritoneum, draining sinuses, wounds, or surgical sites; use of large doses at these sites may result in substantial plasma concentrations of the drug.

5.3 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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients:

Sr. No	Excipients	Grade
1	Macrogol Cetostearyl Ether	BP
2	Cetostearyl alcohol	BP
3	Propylene Glycol	BP
4	Light Liquid Paraffin	BP
5	Disodium Edetate	BP
6	Chlorocresol	USP
7	Sodium Metabisulphite	BP
8	Purified Water	BP

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 Months

6.4 Special precautions for storage

Store below 30^{O} C, do not freeze.

6.5 Nature and contents of container

30 gm Lami tube packed in carton.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements for disposal.

7. APPLICANT/HOLDER OF CERTIFICATE OF PRODUCT REGISTRATION

M/S. NIMO PHARMACEUTICALS LIMITED
NO 29 IRONE AVENUE, AGUDA,
SURULERE, LAGOS,
NIGERIA.

8. DRUG PRODUCT MANUFACTURER

M/S. CURETECH SKINCARE
Plot No, 33-34, phase-IV Bhatoli Kalan,
Baddi. Distt. Solan, (H.P.) 173205
India

9. NAFDAC REGISTRATION NUMBER(S): New Registration