



BRAND NAME:	ALBETA-N CREAM
GENERIC NAME:	CLOTRIMAZOLE, BETAMETHASONE DIPROPIONATE & NEOMYCIN SULPHATE CREAM

1.3 PRODUCT INFORMATION

1.3.1 SUMMARY OF PRODUCT CHARACTERISTICS (SMPC)

Enclosed



BRAND NAME:	ALBETA-N CREAM
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1. Name of drug product

ALBETA-N CREAM
CLOTRIMAZOLE, BETAMETHASONE DIPROPIONATE & NEOMYCIN SULPHATE CREAM

1.1 (Trade) name of product

ALBETA-N CREAM

1.2 Strength

Each gram Contains:
Clotrimazole USP.....1.00 % w/w
Betamethasone Dipropionate
Eq. to Betamethasone USP.....0.05 % w/w
Neomycin Sulphate USP.....0.50 % w/w
Preservative-Chlorocresol USNF.....0.10 % w/w
Cream Base.....Q.S.

1.3 Pharmaceutical Dosage Form

Cream

Description: White coloured homogeneous cream.



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2. QUALITATIVE & QUANTITATIVE COMPOSITION

2.1 Qualitative Declaration

ALBETA-N CREAM

Each gram Contains:

Clotrimazole USP.....1.00 % w/w

Betamethasone Dipropionate

Eq. to Betamethasone USP.....0.05 % w/w

Neomycin Sulphate USP.....0.50 % w/w

Preservative-Chlorocresol USNF.....0.10 % w/w

Cream Base.....Q.S.

2.2 Quantitative Declaration

Batch Formula: Batch Size: 750 Kgs

S. No.	Name of the ingredients	Reference Standards	Function	Label Claim	Quantity per unit dose
1.	Clotrimazole	USP	Active	1.0 %	7.500 Kg
2.	Betamethasone Dipropionate eq. to Betamethasone	USP	Active	0.05 %	0.482 Kg
3.	Neomycin Sulphate	USP	Active	0.5 %	4.050 Kg
4.	Chlorocresol	USNF	Preservative	0.1 %	0.750 Kg
5.	Cetostearyl Alcohol	BP	Emulsion Stabilizer	---	45.00 Kg
6.	Cetomacragol 1000	BP	Emulsifier	---	13.50 Kg
7.	Light Liquid Paraffin	BP	Soothing Agent	---	30.00 Kg
8.	White Soft Paraffin	BP	Soothing Agent	---	75.00 Kg
9.	B.H.T.	BP	Antioxidant	---	0.147 Kg
10.	Sodium Dihydrogen Phosphate	BP	Buffer	---	2.270 Kg
11.	Propylene Glycol	BP	Solvent	---	60.000 Kg
12.	Purified Water	--	Cream Base	---	q. s.



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3. PHARMACEUTICAL DOSAGE FORM

Cream

White coloured homogeneous cream.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

ALBETA-N CREAM is indicated for topical application in the treatment of fungal infection of skin, such as tinea manus, tinea pedis, tinea cruris, tinea corporis and tinea versicolor. It is also proved effective on the treatment of many kinds of der matitis, eczema and pruritus.

4.2 Posology and Method of Administration

Wash the affected area with soap water & dry with clean cloth. Apply ALBETA-N CREAM over the affected area. Repeat the application after every three hours. Generally the duration of application depends on the type of infecting organism; Treat as below for the following: Tinea corporis, 2 weeks, tinea cruris. 2 weeks, Tinea pedis, 4 weeks, Tinea manus: 4 weeks, infection normally resistant to antifungal agents; 4 to 6 weeks.

4.3 Contraindications

Use of Betamethasone + Clotrimazole + Neomycin is considered to be harmful for patients with known allergy to any of the components or excipients of this medicine. Avoid its use in case of any fungal infections (ringworm or athlete's foot), viral infections (herpes or chickenpox) or for treatment of acne or rosacea. Consult your doctor before using it for any condition.

4.4 Special Warnings and Precautions for Use

For external use only.

Avoid contact with eyes.

Do not exceed prescribed dosage. Read carefully before using.

Application to the face or on large areas for longer periods of time than recommended in Leaflet should be under the supervision of a physician.



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4.5 Interaction with other medicinal products and other forms of interaction

Because little, if any of ketoconazole cream is absorbed into the blood, the risk of it. Interacting with another medicine is low. Caution should be exercised when using drugs like Carbamazepine, Cyclosporine and oral hypoglycemic agent's especially patient with extensive skin damage whereby there may be increased absorption.

Neomycin also may impair the absorption of drugs like digoxin, methotrexate, some vitamins and oral contraceptive in such instance.

4.6 Fertility, pregnancy and lactation

Adequate human data on use during pregnancy are not available.

Adequate human and animal data on use during lactation are not available.

4.7 Effects on ability to drive and operate machine

No studies on the effects on the ability to drive and use machines have been performed

4.8 Undesirable effects

Burning, tingling, dry skin, or stinging may occur. If any of these effects persist or worsen, notify your doctor or pharmacist promptly.

Remember that your doctor has prescribed this medication because he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects.

Tell your doctor right away if any of these unlikely but serious side effects occur: extreme hair growth, skin thinning/discoloration, acne, stretch marks, "hair bumps" (folliculitis).

Rarely, it is possible this medication will be absorbed from the skin into the bloodstream.

This can lead to side effects of too much corticosteroid. These side effects are more likely in children, and in people who use this medication for a long time or over large areas of the skin.

Tell your doctor right away if any of the following side effects occur:

unusual/extreme tiredness, weight loss, headache, swelling ankles/feet, increased thirst/urination, vision problems.



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A very serious allergic reaction to this drug is rare. However, seek immediate medical attention if you notice any of the following symptoms of a serious allergic reaction: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

4.9 Overdose

Acute overdosage with topical application of ALBETA-N 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 ALBETA-N CREAM. Signs of toxicology appearing after such accidental ingestion should be treated symptomatically.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Cream contains the dipropionate ester of betamethasone, a glucocorticoid exhibiting the general properties of corticosteroids, and clotrimazole which is an imidazole antifungal agent. 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 Trichomonas, Staphylococci and Bacteroides. Neomycin is an aminoglycoside antibiotic that primarily exerts its effect on bacterial cells by inhibiting polypeptide assembly and synthesis on the ribosome.

5.2 Pharmacokinetic properties

Cream intended for treatment of skin conditions and is applied topically. Thus there are minimal pharmacokinetic aspects related to bioavailability at the site of action.

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

The extent of percutaneous absorption of topical corticosteroids is determined by many factors including vehicle, integrity of skin and use of occlusion.

Systemically absorbed topical corticosteroids are bound to plasma proteins metabolized in the liver and excreted by the kidneys. Some corticosteroids and their metabolites are also excreted in the bile.

Neomycin is poorly absorbed from the gastrointestinal tract and after topical administration an



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insufficient amount is absorbed to produce systemic effects. Absorption has been reported to occur from wounds and inflamed skin. After absorption neomycin is rapidly excreted by the kidneys in active form.

5.3 Pre-clinical safety data

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

6. Pharmaceutical particulars

6.1 List of excipients

Chlorocresol

Cetostearyl Alcohol

Cetomacragol 1000

Light Liquid Paraffin

White Soft Paraffin

B.H.T.

Sodium Dihydrogen Phosphate

Propylene Glycol

Disodium EDTA

Purified Water

6.2 Incompatibilities

Not Applicable

6.3 Shelf-Life

36 months

6.3 Special Precautions for Storage

Store below 30⁰C.

For External Use only.

Do not freeze.

KEEP MEDICINES OUT OF REACH OF CHILDREN.



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6.4 Nature and Contents of Container

30 gm Lami tube

7. Marketing authorization holder



MAXHEAL PHARMACEUTICALS (INDIA) LTD.

J-7, M.I.D.C, TARAPUR INDUSTRIAL AREA,
BOISAR-401506, DIST. PALGHAR, INDIA

8. Marketing authorisation number(s)

NA

9. Date of first authorisation/renewal of the authorization

NA

10. Date of revision of the text

NA