NELBACT CREAM
(Clotrimazole, Betamethasone And Neomycin Sulfate Cream)
Summary of Product Characteristics (SmPC)

1. NAME OF THE MEDICINAL PRODUCT

1.1 Name of the Medicinal Product

NELBACT CREAM

(Clotrimazole USP 1.0 % W/W, Betamethasone Dipropionate USP 0.05 % W/W and Neomycin Sulfate 0.50 % W/W Cream)

Pharmaceutical Form : Semisolid Cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Clotrimazole USP	1.0 % W/W
Betamethasone Dipropionate U.S.P.	
Equivalent to Betamethasone	0.05 % W/W
Neomycin Sulfate USP	0.50 % W/W
Cream base	QS
Preservative-Chlorocresol USP / NF	0.10 % W/W

Standard Batch Size 1000 kg

Sr. No.	Ingredient	Label claim	% Content	O.A. (in %)	Std. Qty. (Kg)	Reason For inclusion
1	Clotrimazole	1% W/W	1%	2 %	10.200	Active
2	Betamethasone Dipropionate	0.05% W/W	0.05%	10 %	707.150 gm	Active
3	Neomycin Sulfate	0.50% W/W	0.50%	10 %	5.500	Active
4	Chlorocresol	0.10% W/W	0.10%	--	1.000	Preservative
5	Cetostearyl Alcohol BP	--	7.2%	--	72.000	Consistency building agent
6	Cetomacrogol 1000 (Cetodet 500)	--	2%	--	20.000	Emulsifying agent
7	Light Liquid Paraffin	--	3.5%	--	35.000	Emollient
8	White Soft Paraffin	--	20%	--	200.00	Emollient
9	Methyl Paraben	--	0.16%	--	1.600	Preservative
10	Propyl Paraben	--	0.04%	--	0.400	Preservative
11	Propylene Glycol	--	10%	--	100.00	Humectant
12	Disodium EDTA	--	0.01%	--	0.100	Chelating agent
13	Di Sodium Hydrogen Orthophosphate (Anhydrous)	--	0.015%	--	0.150	Emulsifier
14	Sodium Dihydrogen Orthophosphate	--	0.07%	--	0.700	Emulsifier
15	Titanium Dioxide (Micronised)	--	0.25%	--	2.500	Opacifier
16	Lavender FR-3872 Perfume	--	0.1%	--	1.000	Fragrant
17	Purified Water	--	q.s.	--	q.s.	Vehicle

3. PHARMACEUTICAL FORM

White colour cream

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

NELBACT CREAM is indicated for the treatment of the following conditions where secondary bacterial infection is present, suspected, or likely to occur: eczema in adults and children (aged 2 years and over), 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.

For the treatment of :

i. All dermatomycoses due to moulds and other fungi (e.g. Trichophyton species)

ii. All dermatomycoses due to yeasts (Candida species). These include ringworm (tinea) infections (e.g. athlete's foot), paronychia, pityriasis versicolor, erythrasma and intertrigo.

iii. Skin diseases showing secondary infection with these fungi.

iv. Candidal znappy rash, vulvitis and balanitis.

4.2 Posology and method of administration

Route of administration: Cutaneous

The cream is especially appropriate for moist or weeping surfaces, and the ointment for dry lichenified or scaly lesions, but this is not invariably so.

In adults, in the more resistant lesions, such as the thickened plaques of psoriasis on elbows and knees, the effects of this medicinal product can be enhanced, if necessary, by occluding the treatment area with polythene film. Overnight occlusion only is usually adequate to bring about a satisfactory response in such lesions, thereafter improvement can usually be maintained by regular application without occlusion.

Treatment should not be continued for more than 7 days without medical supervision

Adults and children aged 2 years and over:

A small quantity should be applied to the affected area two or three times daily until improvement occurs. It may then be possible to maintain improvement by applying once a day or even less often.

Use this medication on the skin only. Clean and thoroughly dry the area to be treated. Apply a thin layer of the medication to the affected area and gently rub in, usually twice daily (in the morning and evening) or as directed by your doctor. Wash your hands after using unless you are using this medication to treat the hands. Do not wrap, cover, or bandage the area unless directed to do so by your doctor. Wear loose-fitting clothes after applying the medication to the groin area.

Do not apply the medication in the eyes, nose, mouth, or inside the vagina. If you do get the medication in those areas, flush with plenty of water.

4.3 Contraindications

• Rosacea.

• Acne vulgaris.

• Perioral dermatitis.

• Perianal and genital pruritus.

• Primary cutaneous viral infections (e.g. herpes simplex, chickenpox).

• Hypersensitivity to any component of the preparation.

• Use is not indicated in the treatment of primary infected skin lesions caused by infection with fungi or bacteria; primary or secondary infections due to yeast; or secondary infections due to Pseudomonas or Proteus species.

• Dermatoses in children under 2 years of age, including dermatitis and napkin eruptions.

A possibility of increased absorption exists in very young children thus this medicinal product is not recommended for use in neonates and infants (up to 2 years). In neonates and infants, absorption by immature skin may be enhanced, and renal function may be immature.

• Preparations containing Neomycin should not be used for the treatment of otitis externa when the ear drum is perforated, because of the risk of ototoxicity.

• Due to the known ototoxic and nephrotoxic potential of Neomycin sulphate, the use of NELBACT

CREAM in large quantities or on large areas for prolonged periods of time is not recommended in circumstances where significant systemic absorption may occur.
Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
Do not use the cream to treat nail or scalp infections.
Bacterial, fungal, parasitic or viral infections of the scalp unless simultaneous treatment is initiated.
Hypersensitivity to any component of the preparation.
Dermatoses in children under six years of age.

4.4 Special warnings and precautions for use

Betamethasone+Clotrimazole+Neomycin should not be used on the face and contact with eyes should be avoided. Do not apply a bandage or dressing on the area being treated, as this will increase absorption of the medicine and increase the risk of side-effects. This medicine should only be used for the condition it is prescribed for. Do not use it for any other condition without consulting your doctor. Do not give it to other people even if their condition appears to be the same.

Warnings

FOR EXTERNAL USE ONLY.
Do not use with a heating pad. Keep away from children to avoid accidental poisoning Do not swallow . If swallowed, induce vomiting and call a physician .
Keep away from eyes. If skin redness or irritation develops, call a physician .

Precautions

Long-term continuous topical therapy should be avoided where possible, particularly in infants and children, as adrenal suppression, with or without clinical features of Cushing's syndrome, can occur even without occlusion. In this situation, topical steroids should be discontinued gradually under medical supervision because of the risk of adrenal insufficiency.
If infection persists, systemic chemotherapy is required.
Withdraw topical corticosteroid if there is a spread of infection.
Bacterial infection is encouraged by the warm, moist conditions induced by occlusive dressings, and the skin should be cleansed before a fresh dressing is applied.

Avoid prolonged application to the face. The face, more than other areas of the body, may exhibit atrophic changes after prolonged treatment with potent topical corticosteroids. This must be borne in mind when treating such conditions as psoriasis, discoid lupus erythematosus and severe eczema.

If applied to the eyelids, care is needed to ensure that the preparation does not enter the eye, as glaucoma might result. If NELBACT does enter the eye, the affected eye should be bathed in copious amounts of water.

Topical corticosteroids may be hazardous in psoriasis for a number of reasons including rebound relapses, development of tolerance, risk of generalised pustular psoriasis and development of local or systemic toxicity due to impaired barrier function of the skin. If used in psoriasis careful patient supervision is important.

Extended or recurrent application may increase the risk of contact sensitisation.

Extension of infection may occur due to the masking effect of the steroid.

Following significant systemic absorption, aminoglycosides such as Neomycin can cause irreversible ototoxicity; and Neomycin has nephrotoxic potential.

In renal impairment the plasma clearance of Neomycin is reduced.

Products which contain antimicrobial agents should not be diluted.

This product contains cetostearyl alcohol, which may cause local skin reactions (e.g. contact dermatitis).

4.5 Interaction with other medicinal products and other forms of interaction

Antagonism with polyene antibiotics.

Following significant systemic absorption, Neomycin sulphate 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

Contraindicated; since Neomycin is contraindicated in pregnancy, the combination generic cannot be used in pregnant woman

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

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.

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

This medicine may be harmful if swallowed.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics 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 Trichomones, 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

Pharmacokinetics

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 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 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 Excipient

Cetostearyl Alcohol , Cetomacrogol 1000 , Light Liquid Paraffin, White Soft Paraffin, Methyl Paraben, Propyl Paraben, Propylene Glycol, Disodium EDTA, Di Sodium Hydrogen Orthophosphate (Anhydrous), Sodium Dihydrogen Orthophosphate, Titanium Dioxide (Micronised).

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months from the date of manufacturing.

6.4 Special precautions for storage

FOR EXTERNAL USE ONLY.

Store in a cool dry place, below 30˚C, protect from the light

DO NOT FREEZE.

Keep Medicines out of reach of children.

To be used only under medical supervision.

6.5 Nature and contents of container

30 gm tube packed in Inner carton with leaflets. such 12 inner cartons packed in one Outer carton. Such 1 outer carton wrapped with PVC shrink.

6.6 Special precautions for disposal and other Special handling

No special requirements

7. APPLICANT / MANUFACTURER

ENICAR PHARMACEUTICALS PVT.LTD.

Plot No J-214,215,216, MIDC, Tarapur,

Boisar-401506, Dist.- Palghar,

Maharashtra state, India.

Ph. - +91-2525-279918 / 19 Fax - +91-2525-273523