

NICBACT
(CLOTRIMAZOLE, BETAMETHASONE DIPROPIONATE
NEOMYCIN SULFATE & CHLOROCRESOL CREAM)

1.3 Product Information

1.3.1 Summary of product characteristics (SmPC)

1.3.1.1 Name of the medicinal product:

NICBACT
(CLOTRIMAZOLE, BETAMETHASONE DIPROPIONATE, NEOMYCIN SULFATE &
CHLOROCRESOL CREAM)

1.3.1.2 Qualitative and quantitative composition:

Composition: -

Clotrimazole USP 1.0% W/W

Betamethasone Dipropionate USP equivalent to Betamethasone 0.05% W/W

Neomycin Sulfate USP 0.5% W/W

Chlorocresol USP/NF 0.1% W/W

Cream Base (- QS)

Sr. No.	Ingredients	Specification	Label Claim w/w	Over-ages added (In %)	Quantity in % w/w	Reason for Function
1.	Clotrimazole	USP	1.00%	2%	1.0200%	Medicament
2.	Betamethasone as Dipropionate	USP	0.05% 0.0642	2%	0.0655%	Medicament
3.	Neomycin Sulphate	USP	0.5%	20%	0.6000%	Medicament
4.	Light liquid paraffin	BP	NA	NA	12.8200%	Emollient
5.	Propylene Glycol	BP	NA	NA	4.0000%	Solvent
6.	Hard paraffin Wax	BP	NA	NA	3.0000%	Emollient
7.	Micro Crystalline Wax	IH	NA	NA	1.0000%	Thickening agent
8.	Cetostearyl Alcohol	BP	NA	NA	8.0000%	Thickening Agent, Stabilizing Agent
9.	Benzyl Alcohol	BP	NA	NA	1.0000%	Preservative
10.	Cetomacrogol 1000	IH	NA	NA	2.0000%	Emollient
11.	Chlorocresol	USP/NF	NA	NA	0.1000%	Preservative
12.	Butylated Hydroxytoluene	BP	NA	NA	0.0500%	Preservative
13.	Purified Water	IH	NA	NA	66.3450%	Vehicle

1.3.1.3 Pharmaceutical form: Cream

Description: White coloured cream

1.3.1.4 Clinical Particulars

1.3.1.4.1 Therapeutic indications

NICBACT (Clotrimazole, Betamethasone Dipropionate, Neomycin Sulfate & Chlorocresol Cream) is indicated in the treatment of variety of skin conditions (e.g., eczema, dermatitis,

allergies, rash). It reduces the swelling, itching, and redness that can occur in these types of conditions.

1.3.1.4.2 Posology and method of administration

Route: Topical

As directed by physician.

Method of administration

Adults and children over the age of 12 years. Topical administration twice daily for two weeks (tinea cruris, tinea corporis and candidiasis) or for four weeks (tinea pedis).

Paediatric population

This cream is not recommended for children under the age of twelve years.

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

1.3.1.4.3 Contraindications

NICBACT (Clotrimazole, Betamethasone Dipropionate, Neomycin Sulfate & Chlorocresol Cream) is contraindicated in those patients with a history of sensitivity to any of its components or to other corticosteroids or imidazoles.

If irritation or sensitisation develops with the use of **NICBACT** (Clotrimazole, Betamethasone Dipropionate, Neomycin Sulfate & Chlorocresol Cream) cream, treatment should be discontinued and appropriate therapy instituted.

NICBACT (Clotrimazole, Betamethasone Dipropionate, Neomycin Sulfate & Chlorocresol Cream) is contraindicated in facial rosacea, acne vulgaris, perioral dermatitis, napkin eruptions and bacterial or viral infections.

1.3.1.4.4 Special warnings and precautions for use

Precautions:

NICBACT (Clotrimazole, Betamethasone Dipropionate, Neomycin Sulfate & Chlorocresol Cream) can cause local and systemic toxicity, which is common especially following long continued use on large areas of damaged skin and in flexures. If used on the face, courses should be limited to 5 days.

NICBACT (Clotrimazole, Betamethasone Dipropionate, Neomycin Sulfate & Chlorocresol Cream) **SHOULD NOT BE USED WITH OCCLUSIVE DRESSING.**

- Topical corticosteroids may be hazardous in psoriasis for a number of reasons including rebound relapses following the development of tolerance, risk of generalised pustular psoriasis and local and systemic toxicity due to impaired barrier function of the skin.
- 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.
- **NICBACT** (Clotrimazole, Betamethasone Dipropionate, Neomycin Sulfate & Chlorocresol Cream) is not intended for ophthalmic use.
- Visual disturbance may be reported with systemic and topical (including, intranasal, inhaled and intraocular) corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes of visual disturbances which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

Paediatric population

- Long term continuous therapy should be avoided in all children irrespective of age.

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- **NICBACT** (Clotrimazole, Betamethasone Dipropionate, Neomycin Sulfate & Chlorocresol Cream) should not be used with adhesive dressing.
- The safety and effectiveness of **NICBACT** (Clotrimazole, Betamethasone Dipropionate, Neomycin Sulfate & Chlorocresol Cream) has not been established in children below the age of 12.
- If used on children, courses should be limited to 5 days.

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 fontanel's, headaches, and bilateral papilloedema.

NICBACT (Clotrimazole, Betamethasone Dipropionate, Neomycin Sulfate & Chlorocresol Cream) contains:

Cetostearyl alcohol which may cause localised skin reactions (e.g. contact dermatitis).
Propylene glycol which may cause skin irritation. Because this medicine contains propylene glycol, do not use it on open wounds or large areas of broken or damaged skin (such as burns).

1.3.1.4.5 Interaction with other medicinal products and other forms of interaction

NICBACT (Clotrimazole, Betamethasone Dipropionate, Neomycin Sulfate & Chlorocresol Cream) does not normally react with other medicines. However, tell your doctor or pharmacist if you are using or have recently used any other cream or taken any other medicines, including medicines obtained without a prescription

1.3.1.4.6 Pregnancy and Lactation

Pregnancy

There is inadequate evidence of safety in pregnancy. Clotrimazole has shown no teratogenic effect in animals but is foetotoxic at high oral doses.

Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development including cleft palate and intra-uterine growth retardation. There may therefore be a very small risk of such effects in human foetus. Hence should only be used in pregnancy if the benefit justifies the potential risk to the foetus and such use should not be extensive i.e. in large amounts or for long periods.

Lactation

It is not known whether the components of **NICBACT** (Clotrimazole, Betamethasone Dipropionate, Neomycin Sulfate & Chlorocresol Cream) are excreted in human milk and therefore caution should be exercised when treating nursing mothers. However, tell your doctor or pharmacist if you are using or have recently used any other cream or taken any other medicines, including medicines obtained without a prescription

1.3.1.4.7 Effects on ability to drive and use machines

NICBACT (Clotrimazole, Betamethasone Dipropionate, Neomycin Sulfate & Chlorocresol Cream) is not likely to affect you being able to drive or use any tools or machines.

1.3.1.4.8 Undesirable effects

Like all medicines **NICBACT** (Clotrimazole, Betamethasone Dipropionate, Neomycin Sulfate & Chlorocresol Cream) can cause side effects, but not everybody gets them:

The most commonly reported side effects are:-

burning and stinging, maculopapular rash, oedema, paraesthesia and secondary infection.

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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, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae miliaria, capillary fragility (ecchymoses), blurred vision and sensitisation.

In children receiving topical corticosteroids, Hypothalamic-pituitary adrenal (HPA) axis suppression (HPA) axis suppression, Cushing's syndrome and intracranial hypertension have been reported.

1.3.1.4.9 Overdose

Acute overdosage with topical application of **NICBACT** (Clotrimazole, Betamethasone Dipropionate, Neomycin Sulfate & Chlorocresol 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.

If you use **NICBACT** (Clotrimazole, Betamethasone Dipropionate, Neomycin Sulfate & Chlorocresol Cream) more than you should, it may cause some burning sensation, redness or swelling. If this occurs, stop using **NICBACT** (Clotrimazole, Betamethasone Dipropionate, Neomycin Sulfate & Chlorocresol Cream) straight away. If you have any further questions on the use of this product, ask your doctor or pharmacist.

If you swallow any cream, tell your doctor straight away.

1.3.1.5 Pharmacological properties

1.3.1.5.1 Pharmacodynamic properties

Clotrimazole is a broad-spectrum antifungal agent that inhibits the growth of pathogenic yeasts by changing the permeability of cell membranes. The action of clotrimazole is fungistatic at concentrations of drug up to 20 mcg/mL and may be fungicidal *in vitro* against *Candida albicans* and other species of the genus *Candida* at higher concentrations. Unfortunately, resistance to clotrimazole, which was rare in the past, is now common in various patient populations.

Clotrimazole is generally considered to be a fungistatic, and not a fungicidal drug, although this contrast is not absolute, as clotrimazole shows fungicidal properties at higher concentrations

Betamethasone Dipropionate is a corticosteroids bind to the glucocorticoid receptor inhibiting pro-inflammatory signals, while promoting anti-inflammatory signals. Corticosteroids have a wide therapeutic window as patients may require doses that are multiples of what the body naturally produces. Patients who require long-term treatment with a corticosteroid should be counselled regarding the risk of hypothalamic-pituitary-adrenal axis suppression and increased susceptibility to infections.

Neomycin Sulfate mediates its bactericidal action by inhibiting bacterial protein synthesis, thereby suppressing the growth and survival of susceptible bacteria. Following oral administration, the duration of bactericidal activity of neomycin ranged from 48 to 72 hours. By decreasing colonic bacteria that produce ammonia, neomycin was shown to be effective as an adjunctive therapy in hepatic coma to improve neurologic symptoms.

Neomycin is active against both gram positive and gram negative organisms, including the major *E. coli* species resident in the colon as well as the enteropathogenic forms of *E. coli*. It is also active against *Klebsiella-Enterobacter* group. Resistant strains of *E. coli*, *Klebsiella* and *Proteus spp.* may emerge from neomycin therapy. Neomycin has no antifungal activity and has some activity against some protozoa

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1.3.1.5.2 Pharmacokinetic properties

NICBACT (Clotrimazole, Betamethasone Dipropionate, Neomycin Sulfate & Chlorocresol Cream) is 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 metabolised in the liver and excreted by the kidneys. Some corticosteroids and their metabolites are also excreted in the bile.

1.3.1.5.3 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.

1.3.1.6 Pharmaceutical particulars

1.3.1.6.1 List of excipients

Light liquid paraffin, Propylene Glycol, Hard paraffin Wax, Micro Crystalline Wax, Cetostearyl Alcohol, Benzyl Alcohol, Cetomacrogol 1000, Chlorocresol, Butylated Hydroxytoluene.

1.3.1.6.2 Incompatibilities

Not applicable

1.3.1.6.3 Shelf life

36 months

1.3.1.6.4 Special precautions for storage

- Store at a temperature below 30° C.
- Do not freeze, Protect from direct sunlight.
- Keep all medicines out of the reach of children.
- Avoid contact with eyes.
- Keep the tube tightly close after use.

1.3.1.6.5 Nature and contents of container

Primary packing : 30 gm of cream filled in lami tube.

Secondary packing: Such one lami tube is packed in a carton along with leaflet.

Tertiary packing: 10 Cartons are packed in a shrink. Such 50 shrinks are packed in 5 ply shipper. Shippers to be sealed with BOPP tape.

1.3.1.6.6 Special precautions for disposal and other handling

None

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ASTAMED
HEALTHCARE (I) PVT. LTD.
CIN: U0420MH1999PTC19829

1.3.1.7 Applicant / Manufacturer

Applicant

Applicant name and address	M/s. DON-J PHARMACY NIG. LTD. 34, Murtala Muhammed Way, Kano State, Nigeria.
Contact person's phone number	
Contact person's email	

Manufacturer

Manufacturer name and address	M/s. ASTAMED HEALTHCARE (I) PVT. LTD. Plot No. 2 & 3, Phase II, Genesis Ind. Complex, Kolgaon, Dist. Thane, Tal. Palghar, 401404 Maharashtra State, India
Contact person's phone number	+91 9920633632/ +91 9967364363
Contact person's email	nayan.thakkar@astamed.com