30gm

Clotrimazole, Betamethasone Dipropionate & Neomycin Sulphate Cream

Donbact
Cream

Antifungal
Antibacterial
Anti-Inflammatory

NAFDAC REG. NO.:

Manufactured by:
LESANTO LABORATORIES
Plot No. 8, 10, 11 & 20,
Survey No., 53, Palghar (East) -401 404

Marketed by:
M/S TOPUGOLIFE PHARMACEUTICAL CO. LTD.
No. 13, Joseph Adobayot Street, Off Sunday Ajiede,
Ago Palace Way, Okota, Lagos Nigeria.
E-mail: topugoliss@hotmail.com

Mfg. Lic. No.:
Batch No.:
Mfg. Date:
Exp. Date:

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COMPOSITION:
Clotrimazole USP.....1.0% w/w
Betamethasone Dipropionate USP
Equivalent to Betamethasone.....0.05% w/w
Neomycin Sulphate USP
Equivalent to Neomycin Base.....0.5% w/w
Cream Base.....q.s.
Preservative: Chlorocresol USP.....0.1% w/w

Storage: Store below 30°C.
Do not freeze.
Dosage: As directed by the Physician.
Keep out of reach of children.
Replace the cap after use.

FOR EXTERNAL USE ONLY

1.3 Product Information

1.3.1 Summary of Product Characteristics (SmPC)

Enclosed.

Module I Administrative Information
Product Name: DONBACT
Generic Name: Clotrimazole, Betamethasone Dipropionate& Neomycin Sulphate Cream

Summary Product Characteristics

1. Name of the proprietary product: - DONBACT

Name of the nonproprietary International Product: Clotrimazole, Betamethasone Dipropionate & Neomycin Sulphate Cream

Route of Administration: Topical

2. Qualitative and Quantitative composition:
Batch size: 300 Kg

Sr. No.	Ingredients	Specifications	Quantity/ Tube (g)	Label Claim (% w/w)	Reason for inclusion
Active					
1.	Betamethasone Dipropionate Equivalent to Betamethasone	USP	0.015	0.05	Active
2.	Clotrimazole	USP	0.300	1.00	Active
3.	Neomycin Sulfate Equivalent to Neomycin Base	USP	0.220	0.50	Active
Excipients					
4.	Methyl Hydroxybenzoate	BP	0.045	--	Preservative
5.	Propyl Hydroxybenzoate	BP	0.015	--	Preservative
6.	Disodium Edetate	BP	0.030	--	Chelating agent
7.	Chlorocresol	USP	0.030	0.10	Preservative
8.	Cetomacrogol 1000	IH	0.750	--	Oil Phase
9.	Cetostearyl Alcohol	BP	3.000	--	Oil Phase
10.	Light Liquid Paraffin	BP	0.660	--	Oil Phase
11.	White Soft Paraffin	BP	4.800	--	Oil Phase
12.	Glycerol	BP	3.000	--	Emollient
13.	Propylene Glycol	BP	3.000	--	Humectant
14.	Lavender Oil	BP	q.s.	--	Perfume

USP = United State Pharmacopoeia

BP = British Pharmacopoeia

IH = In-House Specification

q.s. = Quantity Sufficient

3. Pharmaceutical Form: Topical

4. Clinical Particulars:

4.1 Therapeutic Indications

Clotrimazole, Betamethasone Dipropionate & Neomycin Sulphate Cream is indicated in the treatment of various inflammatory dermatological disorders superadded with bacterial or superficial fungal infections of the skin.

4.2 Posology and method of administration:

Clotrimazole, Betamethasone Dipropionate & Neomycin Sulphate Cream should be thinly and evenly applied to the affected area two or three times a day with a gentle rub.
To be used under medical supervision only.

4.3 Contraindications

1. Hypersensitivity to any of the ingredients.
2. Viral or tubercular infections of the skin.

4.4 Special warnings and precautions for use

The following side effects have been reported with topical corticosteroid medications: itching, irritation, dryness, infection of the hair follicles, increased hair, acne, change in skin color, allergic skin reaction, skin thinning and stretch marks.

4.5 Interaction with other medicinal products and other forms of interaction

The concomitant use of other drugs or over the counter products at the same time, the effects of cream may change. This may increase the risk for side – effects or cause the drug not to work properly. It may interact with the Amphotericin B, Flucytosine and Nystatin.

4.6 Pregnancy and lactation

This drug is classified by FDA as pregnancy category 'B' **No risk in other studies:** Animal reproduction studies have failed to demonstrate a risk to the fetus and there are no adequate and well- controlled studies in pregnant women OR Animal studies have shown an adverse effect, but adequate and well-controlled studies in pregnant women have failed to demonstrate a risk to the fetus in any trimester.
This medicine is relatively safe to use while breast feeding but should not be applied anywhere near breast. Make sure the baby doesn't come in to contact with the cream and use this medicine only when clearly needed.

4.7 Effects on ability to drive and use machines

NA

4.8 Undesirable Effects

Adverse reactions reported for Cream in clinical trials were paresthesia in 1.9% of patients, and rash, edema, and secondary infection, each in less than 1% of patients.

The following local adverse reactions have been reported with topical corticosteroids and may occur more frequently with the use of occlusive dressings. These reactions are listed in an approximate decreasing order of occurrence: itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae, and miliaria. In the pediatric population, reported adverse events for Cream include growth retardation, benign intracranial hypertension, Cushing's syndrome (HPA axis suppression), and local cutaneous reactions, including skin atrophy.

Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria in some patients.

Adverse reactions reported with the use of clotrimazole are as follows: erythema, stinging, blistering, peeling, edema, pruritus, urticaria, and general irritation of the skin.

4.9 Overdose

If high doses are taken watery stools (diarrhoea), abdominal cramps and a clinically significant loss of fluid, potassium and ot Amounts greater than 45 g/week of Cream should not be used. Acute overdosage with topical application of Cream is unlikely and would not be expected to lead to life-threatening situation. This Cream should not be used for longer than the prescribed time period.

Topically applied corticosteroids, such as the one contained in cream can be absorbed in sufficient amounts to produce systemic effects.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

Pharmacotherapeutic group:

Betamethasone Dipropionate - Anti-inflammatory

Clotrimazole - Antifungal

Neomycin Sulphate - Antibacterial

ATC code:

Betamethasone Dipropionate - D07AC01

Clotrimazole - D01AC01

Neomycin Sulphate- D06AX04

Clotrimazole,Betamethasone Dipropionate & Neomycin Sulphate Cream is a combination of a synthetic antifungal agent Clotrimazole; a broadspectrum antibacterial antibiotic Neomycin sulphate; and a potent topical corticosteroid Betamethasone dipropionate.

Clotrimazole,Betamethasone Dipropionate & Neomycin Sulphate Cream provides a comprehensive treatment for various inflammatory dermatological disorders superadded with bacterial or superficial fungal infections of the skin. Betamethasone dipropionate is one of the most potent topical corticosteroid available and rapidly controls the symptomssuch 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 superficial fungal infections of the skin. Neomycin sulphate is a broad spectrum antibacterial. Hence, Clotrimazole,Betamethasone Dipropionate & Neomycin Sulphate Cream effectively controls inflammatory disorders superadded with bacterial and/or fungal infections of the skin.

5.2 Pharmacokinetics properties

Pharmacokinetic investigations after vaginal application have shown that only asmall amount of cream is absorbed. Due to rapid hepatic metabolism of absorbed cream into pharmacologically inactive metabolites, the resulting peak plasma concentrations of cream after vagin al application of a 500-mg dose were <10 ng/mL, reflecting that cream applied intravaginally does not lead to measurable systemic effects or side effects.

5.3 Preclinical safety data

There are no pre-clinical data.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

INGREDIENTS	SPECIFICATION
Methyl Paraben	British Pharmacopoeia
Propyl Paraben	British Pharmacopoeia
Disodium Edetae	British Pharmacopoeia
Chlorocresol	United State Pharmacopoeia
Cetomacrogol 1000	In-House Specification
Cetostearyl Alcohol	British Pharmacopoeia
Light Liquid Paraffin	British Pharmacopoeia
White Soft Paraffin	British Pharmacopoeia
Glycerin	British Pharmacopoeia
Propylene Glycol	British Pharmacopoeia
Lavender Oil	British Pharmacopoeia

6.2 Incompatibilities

Not Applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store below 30 ^{0} C cool, dry place.

6.5 Nature and contents of container

30 g Lami tube filled and sealed to be packed in a primary carton along with the Pack Insert.

7. Special precautions for disposal and other handling

No special requirements.

8. MARKETING AUTHORIZATION HOLDER

NA

Module I Administrative Information

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Generic Name: Clotrimazole, Betamethasone Dipropionate& Neomycin Sulphate Cream