NATIONAL AGENCY FOR FOOD & DRUG ADMINISTRATION & CONTROL (NAFDAC)

Registration & Regulatory Affairs (R & R) Directorate

Product Name

FRESHBACT CREAM

(Clotrimazole, Betamethasone and Neomycin Cream)

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

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1. Name of the Medicinal Product

FRESHBACT CREAM

(Clotrimazole, Betamethasone and Neomycin Cream)

2. Qualitative and Quantitative Composition

Composition

Clotrimazole USP 1.0% w/w

Betamethasone Dipropionate USP

Eq. to Betamethasone 0.05% w/w

Neomycin Sulphate USP 0.5% w/w

Cream Base q.s.

3. Pharmaceutical Form

Cream

4. Clinical Particulars

4.1 Therapeutic indications

Clotrimazole, Betamethasone and Neomycin Cream is indicated for the relief of the inflammatory manifestatios of corticosteroid responsive dermatoses when complicated by secondary infection caused by organism sensitive to the components of this dermatologic preparation or when the possibility of such infection is suspected.

4.2 Posology and method of administration

Dosage and Administration

A small quantity of Clotrimazole, Betamethasone and Neomycin cream should be applied to cover completely the affected area two or three times daily, or as prescribed by the physician. Frequency of application should be determined according to severity of the condition.

During the therapy should be determined by patient response. In cases of tineapedis, longer therapy should be determined by patient response. In cases of tineapedis, longer therapy (2-4 weeks) may be necessary.

4.3 Contraindications

Clotrimazole, Betamethasone and Neomycin Cream is contra-indicated in those patients with a history known sensitivity reactionsto to any of its components.

4.4 Special warning and special precaution for use

Not Applicable

4.5 Interaction with other medicinal products and form of interaction

Not Applicable

4.6 Pregnancy and lactation

Clotrimazole

Fertility:

No human studies of the effects of clotrimazole on fertility have been performed; however, animal studies have not demonstrated any effects of the drug on fertility.

Pregnancy:

There is a limited amount of data from the use of clotrimazole in pregnant women. Animal studies with clotrimazole have shown reproductive toxicity at high oral doses. At the low systemic exposures of clotrimazole following topical treatment, harmful effects with respect to reproductive toxicity are not predicted. Clotrimazole can be used during pregnancy, but only under the supervision of a physician or midwife.

Lactation:

Available pharmacodynamic/toxicological data in animals have shown excretion of clotrimazole/metabolites in milk after intravenous administration. A risk to the suckling child cannot be excluded. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from clotrimazole therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.

Betamethasone Dipropionate:

There are no adequate and well controlled studies of the teratogenic potential of topically applied corticosteroids in pregnant women. Therefore topical steroids should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus. It is not known whether topical administration of corticosteroids would result in sufficient systemic absorption to produce detectable quantities in breast milk. Systemically administered corticosteroids are secreted into breast milk in quantities not likely to have a deleterious effect on the infant. Nevertheless, a decision should be made whether to discontinue the drug, taking into account the importance of the drug to the mother.

Neomycin Sulphate

Neomycin cannot be detected in the blood following application of Neomycin and its use is unlikely to have any effect on the foetus or on breast feeding.

4.7 Effects on ability to drive and use machines

Not Applicable

4.8 Undesirable effects

The most frequent adverse reactions reported were burning, irritation, itching and stinging sensation. Less frequent adverse reactions were itching, skin atrophy, cracking and fissuring of the skin, stinging, cracking, erythema, folliculitis, numbness of fingers, skin atrophy and telangiectasia.

Adverse eventas that may occur with use of topical clotrimazole preparations include: erythema, stinging, burning, pruritis, urticaria and edema. Contact dermatitis may occur rarely.

Neomycin occasionally causes skin sensitization, ototoxicity and nephrotoxicity have been reported. The reaction most frequently occurring is allergic sensitization.

4.9 Overdose

SYMPTOMS: Excessive or prolonged use of topical corticosterois can suppress pituitary adrenal function, resulting in secondary adrenal insufficiency and produce manifestations of hypercorticism including cushing disease.

Excessive or prolongeduse of topical antibiotic lead to overgrowth of lessions by nonsusceptible organisms.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Vasoconstrictor Assay

Studies performed with clotrimazole and betamethasone dipropionate cream indicate that these topical combination antifungal/corticosteroids may have vasoconstrictor potencies in a range that is comparable to high-potency topical corticosteroids. However, similar blanching scores do not necessarily imply therapeutic equivalence.

5.2 Pharmacokinetic properties

Topical corticosteroids can be absorbed from normal intact skin. The extent of percutaneous absorption of topical corticosteroids is determined by many factors, including the vehicle and the integrity of the epidermal barrier. Inflammation and/or other disease process in the skin may increase percutaneous absorption. Systemic absorption following use of topical clotrimazole preparation is very low. Estimated bioavailability is less than 0.5 % clotrimazole concentrations achieved in the

epidermal layers exceed the minimal inhibitory concentrations (MICs) for almost all pathogenic fungi.

5.3 Preclinical Studies

Not Applicable

6.0 PHARMACEUTICAL EXCIPIENTS

6.1 List of excipients

S. NO	INGREDIENTS	GRADE
1.	BENZYL ALCOHOL	BP
2.	CETOSTEARYL ALCOHOL	BP
3.	CETOMACROGOL-1000	BP
4.	WHITE SOFT PARAFFIN	BP
5.	LIQUID PARAFFIN	BP
6.	SODIUM DIHYDROGEN PHOSPHATE	BP
7.	PEG-400	BP
8.	PURIFIED WATER	BP

6.2 Incompatibilities

Not Applicable

6.3 Shelf life

36 months.

6.4 Special precaution for storage

Store at temperature not exceeding 30°C. Protect from light.

6.5 Nature contents of container

30 gm Aluminum collapsible tube with screw capped in a carton.

6.6 Instruction for use handling and disposal

Keep out of reach of children.

7. Manufacturer name

ALPA LABORATORIES LIMITED
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FRESHBACT CREAM
(Clotrimazole, Betamethasone and Neomycin Cream)

8. **Marketing Authority**

FRESHBORN INDUSTRIES LTD.

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Satellite Town, Lagos State, Nigeria.