National Agency for Food & Drug Administration & Control (NAFDAC)

Registration & Regulatory Affairs (R & R) Directorate

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC) TEMPLATE

1. NAME OF THE MEDICINAL PRODUCT

FECCOX Clotrimazole, Betamethasone and Neomycin Cream
(Clotrimazole, Betamethasone and Neomycin Cream)

2. QUALITATIVE AND QUANTITATIVECOMPOSITION

Clotrimazole USP 1.00 % w/w
Betamethasone Dipropionate USP
Eq. to Betamethasone 0.05 % w/w
Neomycin Sulphate USP 0.5 % w/w
Chlorocresol (As Preservative) USP 0.1 % w/w

3. PHARMACEUTICAL FORM

Cream

4. Clinical particulars

4.1 Therapeuticindications

FECCOX Cream (Betamethasone Dipropionate/Neomycin/Clotrimazole) is a topical medication used to prevent the growth of fungal cells. It is primarily used for athlete`s foot and jock itch although it can also benefit many other fungal based skin infections.

4.2 Posology and method ofadministration

Route of administration
Topical.

Posology
Always administer FECCOX Cream (Betamethasone dipropionate/Neomycin/Clotrimazole) as you have been prescribed and instructed by your physician. Most patients are advised to dose twice per day, for a period of 2 to 4 weeks depending on the severity of the condition being treated Wash your hands using soap, both before, and after administration. Wash the area of skin to be treated.
Massage a small amount of the cream into the skin, leaving a thin layer of the cream behind to air dry. Do not bandage unless specifically recommended by your physician.

4.3 Contraindications

FECCOX Cream (Betamethasone Dipropionate/Neomycin/Clotrimazole) is generally well tolerated.
Despite this, patients should report all side effects they notice to their physician.
Possible side effects include:
Irritation
Itching
Peeling
Redness
Inflammation
Stinging sensations
Burning sensations
Seek immediate medical attention if you experience any of the following.
Edema
Pigmentation changes
Atrophy

Growth changes
Stretch marks
Cushing`s syndrome
Symptoms of an allergic or hypersensitive reaction (such as difficulty breathing or swallowing, chest pains,
skin rash, hives, or swelling)

4.4 Special warnings and precautions for use

1. If you have an allergic or hypersensitive reaction, seek emergency medical attention.
2. Possible symptoms include difficulty breathing, difficulty swallowing, swelling, chest tightness, skin rashes, and hives.
3. This medication should only be used as instructed and prescribed by your physician or pharmacist.
Do not alter your dosage unless specifically instructed to do so by either of the above.
4. Dosage and usage often depends on the severity of the condition, as well as the patient's medical history and current health condition.
5. Before you begin using this medication, ensure your physician is aware of the following:
If you are pregnant or breastfeeding.
If you have any allergies.
If you have any other illnesses, disorders, or medical conditions.
If you are using any other drugs or medication.
If you are using any vitamins or supplements.

4.5 Interaction with other medicinal products and other forms ofinteraction

Antagonism with Polyene Antibiotics.

4.6 Pregnancy and Lactation

Pregnancy

Pregnancy Class D There is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans but potential benefits may warrant use of the skin rash, hives, or swelling). drug in pregnant women despite potential risks.

Lactation

Lactation Class L4 There is positive evidence of risk to a breastfed infant or to breastmilk production but the benefits of use in breastfeeding mothers may be acceptable despite the risk to the infant eg if the drug is needed in a lifethreatening situation or for a serious disease for which safer drugs cannot be used or are ineffective.

4.7 Effects on ability to drive and use machines

FECCOX Cream has no influence on the ability to drive and use machines.

4.8 Undesirable effects

FECCOX Cream (Betamethasone Dipropionate/Neomycin/Clotrimazole) is generally well tolerated.
Despite this, patients should report all side effects they notice to their physician.
Possible side effects include:
Irritation
Itching
Peeling
Redness
Inflammation
Stinging sensations
Burning sensations
Seek immediate medical attention if you experience any of the following.
Edema

Pigmentation changes
Atrophy
Growth changes
Stretch marks
Cushing`s syndrome
Symptoms of an allergic or hypersensitive reaction (such as difficulty breathing or swallowing, chest pains, skin rash, hives, or swelling).

4.9 Overdose

Overdose of FECCOX Cream cause the below adverse
effects: Nausea
Stomach upset
Skin rash
Acute toxicity.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

FECCOX Cream contains the dipropionate ester of Baclomethasone dipropionate, 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 a rapidly bactericidal aminoglycoside antibiotic effective against Gram positive organisms including staphylococci and a wide range of Gram negative organisms. Strains of Pseudomonas aeruginosa are resistant to neomycin, as are fungi and viruses.

5.2 Pharmacokinetic properties

FECCOX 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.
Neomycin is either not absorbed or is absorbed only minimally through intact skin. Any neomycin which is absorbed will be rapidly excreted by the kidneys in an unchanged state.

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 ofexcipients

Cetomecrogol 1000 BP
Cetostearyl Alcohol BP
Light liquid Paraffin BP
White Petroleum Jelly BP
Propylene Glycol BP
Chlorocresol USP
Disodium Edetate BP
LAVENDER BP

6.2 Incompatibilities

Not Applicable

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store below 30^0C. Protect from light.

6.5 Nature and contents of container <andspecialequiKpmentforuse,administrationor implantation>

30 GM Lamitube

6.6 Special precautions for disposal <and otherhandling>

No special requirements

6.7 SUBMITTED BY

M/S Feccox Pharm & Gen. Ent Ltd.
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Kano, Kano State, NIGERIA.

6.8 MANUFACTURED BY

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