

SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

C-ZOLE BG (Beclomethasone Dipropionate, Clotrimazole and Gentamicin Sulfate Cream)

1.1 Strength:

Clotrimazole BP.....1.0%w/w

Beclomethasone Dipropionate USP.....0.025%w/w

Gentamicin Sulfate BP

Eq. to Gentamicin0.1%w/w

1.2 Pharmaceutical form: Cream

2. Qualitative and Quantitative composition

Clotrimazole BP.....1.0%w/w

Beclomethasone Dipropionate USP.....0.025%w/w

Gentamicin Sulfate BP

Eq. to Gentamicin0.1%w/w

Cream Base.....q.s.

3. Pharmaceutical form

Semi-Solid Dosage Form (Cream)

4. Clinical particulars

4.1 Therapeutic indications;

Beclomethasone Dipropionate , Clotrimazole and Gentamicin Sulfate Cream is indicated for the relief from Impetigo, Furunculosis, secondary infected dermatoses, Napkin rashes, Otitis externa, Intertriginous eruptions, Atopic and discoid eczema, dermatitis, psoriasis, lichen simplex, discoid lupus erythematosus.

Beclomethasone Dipropionate , Clotrimazole and Gentamicin Sulfate Cream is commonly used for the treatment and prevention of the symptoms of discomfort of many types of skin problems.

Beclomethasone Dipropionate , Clotrimazole and Gentamicin Sulfate Cream is also used for the treatment of a variety of skin conditions such as contact dermatitis, atopic dermatitis, eczema, lichen planus, bug bites, burns, psoriasis, chronic discoid lupus erythematosus, alopecia areata, mycosis fungoides, dermatophyte and fungus or yeast infections.

Beclomethasone Dipropionate , Clotrimazole and Gentamicin Sulfate Cream reduces or inhibits the actions of chemicals in the body that cause inflammation, redness, and swelling. Beclomethasone Dipropionate ,

Clotrimazole and Gentamicin Sulfate Cream works by reducing irritation and itching on the affected areas of the skin. When Beclomethasone Dipropionate , Clotrimazole and Gentamicin Sulfate Cream applied to the skin it is absorbed into the skin cells. Here Beclomethasone Dipropionate , Clotrimazole and Gentamicin Sulfate Cream works by preventing the release of certain chemicals from the cells.

These chemicals are important in the immune system, and are released as a result of allergy or irritation. They cause blood vessels to widen, resulting in the affected area of skin becoming red, swollen, itchy and painful, such as is seen in dermatitis or eczema. By decreasing the release of these chemicals in the skin, Beclomethasone Dipropionate , Clotrimazole and Gentamicin Sulfate Cream reduces inflammation and relieves itch.

Mechanism of Action:

Clotrimazole is a broad-spectrum antifungal which binds to phospholipids in the cell membrane altering cell wall permeability causing a loss in essential intracellular elements.

Beclomethasone controls the rate of protein synthesis, depresses the migration of polymorphonuclear leukocytes and fibroblasts, and reverses capillary permeability and lysosomal stabilization at the cellular level to prevent or control inflammation.

Gentamicin binds to 30s and 50s ribosomal subunits of susceptible bacteria disrupting protein synthesis, thus rendering the bacterial cell membrane defective.

4.2. Posology and method of administration

A thin film of Clotrimazole, Beclomethasone Dipropionate and Gentamicin Sulfate cream should be applied to cover completely the affected and surrounding skin areas twice daily, in the morning and at night.

For treatment to be effective, Clotrimazole, Beclomethasone Dipropionate and Gentamicin Sulfate cream should be applied regularly.

Duration of Treatment Duration of therapy varies depending upon the extent and location of disease and patient response. However, if clinical improvement is not achieved by three to four weeks, diagnosis should be reviewed.

4.3. Contraindications

Clotrimazole, Beclomethasone Dipropionate and Gentamicin Sulfate cream is contraindicated in those patients with a history of sensitivity reactions to any of its components.

4.4. Special warnings and precautions for use

For external use only. Do not use in or around the eye.

4.5. Interaction with other medicinal products and other forms of interaction

There are no known interactions.

4.6. Fertility, pregnancy and lactation

Certain medicines should not be used during pregnancy or breastfeeding. However, other medicines may be safely used in pregnancy or breastfeeding providing the benefits to the mother outweigh the risks to the unborn baby. Always inform your doctor if you are pregnant or planning a pregnancy, before using any medicine.

- This medicine should not be used during pregnancy unless considered essential by your doctor. If it is prescribed by your doctor it should not be used on large areas of skin, underneath airtight dressings, or for prolonged periods of time. Consult your doctor for further information.
- This medicine should not be used during breastfeeding unless considered essential by your doctor. If it is prescribed by your doctor it should not be used on large areas of skin, underneath airtight dressings or for prolonged periods of time. If it is applied to the breasts it should be washed off carefully before breastfeeding and then reapplied afterwards.

4.7. Effects on ability to drive and use machines

Beclomethasone Dipropionate, Clotrimazole and Gentamicin Sulfate Cream has no influence on the ability to drive and use machines.

4.8. Undesirable effects

Beclomethasone Dipropionate , Clotrimazole and Gentamicin Sulfate Cream should be used for short courses only, as prolonged and intensive treatment may cause local atrophic changes in the skin such as stria, thinning, loss of elasticity, dilatation of the superficial blood vessels, telangiectasia and ecchymosis.

Reporting of suspected adverse reactions

Health care professionals are asked to report any suspected adverse reactions via the <https://pv.pharmacyboardkenya.org>

4.9. Overdose

Acute overdose with topical application of Beclomethasone Dipropionate , Clotrimazole and Gentamicin Sulfate 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.

Toxic effects are unlikely to occur following accidental ingestion of Beclomethasone Dipropionate , Clotrimazole and Gentamicin Sulfate Cream. Signs of toxicology appearing after such accidental ingestion should be treated symptomatically.

5. Pharmacological properties

5.1. Pharmacodynamic properties

Beclomethasone Dipropionate

Topical corticosteroids act as anti-inflammatory agents via multiple mechanisms to inhibit late phase allergic reactions including decreasing the density of mast cells, decreasing chemotaxis and activation of eosinophils, decreasing cytokine production by lymphocytes, monocytes, mast cells and eosinophils, and inhibiting the metabolism of arachidonic acid.

Clotrimazole

Clotrimazole acts against fungi by inhibiting ergosterol synthesis. Inhibition of ergosterol synthesis leads to structural and functional impairment of the cytoplasmic membrane.

Gentamicin Sulfate

Gentamicin Sulfate is a wide spectrum antibiotic that provides highly effective topical treatment in primary and secondary bacterial infections of the skin. Gentamicin Sulfate Cream, 0.1% may clear infections that have not responded to other topical antibiotic agents. In primary skin infections such as impetigo contagiosa, treatment three or four times daily with Gentamicin Sulfate Cream, 0.1% usually clears the lesions promptly. In secondary skin infections, Gentamicin Sulfate Cream, 0.1% aids in the treatment of the underlying dermatosis by controlling the infection. Bacteria susceptible to the action of gentamicin sulfate include sensitive strains of *Streptococci* (group A beta-hemolytic, alpha-hemolytic), *Staphylococcus aureus* (coagulase positive, coagulase negative, and some penicillinase-producing strains), and the gram-negative bacteria, *Pseudomonas aeruginosa*, *Aerobacter aerogenes*, *Escherichia coli*, *Proteus vulgaris* and *Klebsiella pneumoniae*.

5.2. Pharmacokinetic properties

Beclomethasone Dipropionate

Absorption

Topical corticosteroids can be systemically absorbed from intact healthy skin. The extent of percutaneous absorption of topical corticosteroids is determined by many factors, including the vehicle and the integrity of the epidermal barrier. Occlusion, inflammation and/or other disease processes in the skin may also increase percutaneous absorption.

Distribution

The use of pharmacodynamic endpoints for assessing the systemic exposure of topical corticosteroids is necessary because circulating levels are well below the level of detection.

Metabolism

Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systemically administered corticosteroids. They are metabolised, primarily in the liver.

Elimination

Topical corticosteroids are excreted by the kidneys. In addition, some corticosteroids and their metabolites are also excreted in the bile.

Clotrimazole

Pharmacokinetic investigations after dermal application have shown that clotrimazole is minimally absorbed from the intact or inflamed skin into the human blood circulation. The resulting peak serum concentrations of clotrimazole were below the detection limit of 0.001 mcg/ml, suggesting that clotrimazole applied topically is unlikely to lead to measurable systemic effects or side effects.

Gentamicin Sulfate

Absorption

Topical gentamicin is readily absorbed from large burned, denuded, or granulating areas but not through intact skin. Absorption of gentamicin is faster and greater with the cream compared to the ointment.

Distribution

Unknown

Metabolism

Not Available

Elimination

Not Available

5.3. Preclinical safety data

Non-clinical data reveal no special hazard for humans based on studies of repeated dose toxicity, genotoxicity and carcinogenicity.

6. Pharmaceutical particulars:

6.1. List of Excipients

Cetomacrogol Emulsifying Wax

Cetostearyl Alcohol

Propylene Glycol

Light Liquid Paraffin

Disodium Edetate

Chlorocresol

Dimethicone

Glyceryl Monosterate

White soft paraffin

Purified Water

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

24 months

6.4. Special precautions for storage

Store at a temperature not exceeding 30⁰ C. protect from light.

Do not freeze.

Keep the tube tightly closed after use.

Keep all Medicines Out of Reached of Children

6.5. Nature and contents of container

The cream is filled in printed laminated tubes with internal lacquer coating and HDPE screw-on caps and enclosed in an outer carton along with pack insert. Pack sizes available are 15g.

6.6. Special precautions for disposal and other handling

No Special requirements.

7. MARKETING AUTHORISATION HOLDER

Galaxy Pharmaceutical Limited

P.O. Box 39107-00623, Nairobi

8. MARKETING AUTHORISATION NUMBER(S)

H2022/CTD7659/14829

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11.01.2022

10. DATE OF REVISION OF THE TEXT

11.01.2022