

Module I Administrative Information

Product Name: Econazole, Triamcinolone & Gentamicin Cream

1.3.1 Summary of Product Characteristics (SmPC)

Enclosed.

Summary Product Characteristics

1. Name of the proprietary product: Econazole, Triamcinolone & Gentamicin Cream

Name of the nonproprietary International Product: Econazole Nitrate , Triamcinolone Acetonide & Gentamicin Sulphate Cream Cream

Route of Administration: Topical

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2. Qualitative and Quantitative composition :

Batch size: 310 kg

Sr. No.	Ingredient	Specification	Label Claim	Qty per gram (in mg)	Qty. / tube (20 gm) (in gm)	Qty. / Batch (in kg)	Reason on inclusion
Active							
1.	Econazole Nitrate	BP	1% w/w	0.01	0.200	3.100	Active.
2.	Triamcinolone Acetonide	BP	0.1% w/w	0.001	0.020	0.310	Active.
3.	Gentamicin Sulphate BP Eq. to	BP	0.1% w/w	0.0021	0.042	0.651	Active.
Excipient							
4.	Cetamacrogal 1000	BP	--	0.018	0.36	5.580	Emulsifying agent
5.	Cetostery Alcohol	BP	--	0.072	1.44	22.320	Viscosity increasing agent
6.	White Soft Paraffin	BP	--	0.18	3.6	55.800	Emollient
7.	Propylene Glycol	BP	--	0.05	1	15.500	Humectant
8.	Liquid Paraffin	BP	--	0.06	1.2	18.6	Emollient
9.	Methyl Paraben	BP	--	0.0002	0.004	0.062	Preservative
10.	Purified water	BP	--	q.s. to 1 gm	q.s. to 20 gm	q.s. to 310 kg	Vehicle

BP = British Pharmacopoeia, q.s = Quantity sufficient

Quantity of Gentamicin Sulphate is calculated on potency basis

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3. Pharmaceutical Form: Cream

4. Clinical Particulars:

4.1 Therapeutic Indications

ECONAZOLE, TRIAMCINOLONE & GENTAMICIN CREAM is used for the treatment, control, prevention, & improvement of the following diseases, conditions and symptoms:

Fungal skin infections

Bacterial infections

Athlete's foot

Jock itch

Ringworm

Corticosteroid-responsive dermatoses

4.2 Posology and method of administration:

Dosage and administration: For Topical use.

Use in the morning and evening. Apply the cream on the affected area 2-4 times daily; depending on the severity of the condition. Course of treatment is 2-4 weeks for the treatment of dermatitis and eczema.

4.3 Contraindications

Hypersensitivity to Econazole, Triamcinolone & Gentamicin Cream is a contraindication.

In addition, Econazole, Triamcinolone & Gentamicin Cream.

should not be used if you have the following conditions:

- 2 weeks before a surgery
- At least 2 weeks before a scheduled surgery
- Breastfeeding
- Hypersensitivity
- Organ transplant
- Pregnancy

4.4 Special warnings and precautions for use

Warnings for use:

Avoid prolonged treatment

Precautions:

Children from 30 months to 6 years old

Infants under 30 months old

First trimester of pregnancy

1. Do not contact with eyes and mucous membrane.

2. In case of burning feeling and swelling, the drug should be discontinued, clean the drug, and seek advice from doctors.

3. Large area use for a long time is not allowed.

4. Children, pregnant woman and breast-feeding women should use under the guidance of doctors.

5. Continuous use should not exceed 4 weeks.

6. Do not use if allergy for the product, allergic people should use in caution.

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7. Do not use if the property has changed.
8. Please put this product where children can not touch.
9. Children should use only under adult supervision.
10. Seek advice from doctors or pharmacists before you use the product if you are using some other medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Contraindications of concomitant use

Econazole + Antivitamins K

Risks and Mechanisms: Regardless of the route of administration of econazole: increased effect of the antivitamin K and hemorrhagic risk.

Course of Action: More frequent INR monitoring. Possible dose adjustment of the antivitamin K during the econazole treatment and after its discontinuation.

Econazole + Phenprocoumon:

Risks and Mechanisms: Regardless of the route of administration of econazole: increased effect of the antivitamin K and hemorrhagic risk.

Course of Action: More frequent INR monitoring. Possible dose adjustment of the antivitamin K during and after stopping the treatment with econazole.

ECONAZOLE, TRIAMCINOLONE & GENTAMICIN CREAM may interact with the following drugs and products:

Aspirin, Azathioprine, Basiliximab, Chlorpropamide, Clopidogrel, Cyclosporine, Daclizumab, Dalteparin, Enoxaparin, Glimepiride, Glipizide, Glyburide, Heparin.

4.6 Pregnancy and Lactation:

Risk of systemic absorption. Use with caution.

Children, pregnant woman and breast-feeding women should use under the guidance of doctors.

4.7 Effects on the ability to drive and use machines

Not Applicable

4.8 Undesirable effects:

Acne rosacea, Acneiform rash, Hypertrichosis, Perioral dermatitis, Pustular rash, Skin depigmentation, Skin dryness, Skin fragility, Worsening of acne rosacea.

Allergic reaction may occur, such as skin burning feeling, itching, etc.

4.9 Overdose:

Give supportive measures and treatment.

5. Pharmacological Particulars:

5.1 Pharmacodynamic properties

Pharmacotherapeutic group:

Econazole Nitrate: Imidazole derivative, Antifungal.

Triamcinolone Acetonide: Glucocorticoid, Topical anti-inflammatory(steroidal).

Gentamicin Sulphate: Aminoglycoside Antibacterials

ATC code:

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Econazole Nitrate: D01AC03

Triamcinolone Acetonide: H02AB08

Gentamicin Sulphate: J01GB03

Mechanism of Action:

Econazole Nitrate:

Econazole exerts its effects by altering cellular membrane and interfering with cellular enzymes. It is active against many fungi, dermatophytes and yeasts as well as some gram positive bacteria.

Triamcinolone Acetonide:

The drug exerts its pharmacological action by penetrating and binding to cytoplasmic receptor protein and causes a structural change in steroid receptor complex. This structural change allows its migration into the nucleus and then binding to specific sites on the DNA which leads to transcription of specific m-RNA, and which ultimately regulates protein synthesis. It exerts more selective glucocorticoid action. It stimulates the enzymes needed to decrease the inflammatory response.

The drug exerts anti-inflammatory and immunosuppressant actions as follows: - 1) Induce lipocortins in macrophages, endothelium, and fibroblasts which inhibits phospholipase A2 and thus decreases the production of Prostaglandins, leukotriens (LT), and platelet activating factor, 2) Causes negative regulation of genes for cytokines in macrophages, endothelial cells and lymphocytes and thus decreases the production of interleukins (IL-1, IL-2, IL-3, IL-6), TNF- α , GM-CSF (granulocyte macrophage colony stimulating factor), Gama interferon and suppresses fibroblast proliferation and T-lymphocyte functions and interferes chemo taxis. 3) Decreases the production of acute phase reactants from macrophages and endothelial cells and interferes complement function. 4) Decreases the production of ELAM-1(Endothelial leukocyte adhesion molecule-1) and ICAM-1(intracellular adhesion molecule-1) in endothelial cells. 5) Inhibit IgE mediated histamine and LT-C4 release from basophiles and the effects of antigen-antibody reaction is not mediated 6) Reduces the production of collagenase and stromolysin and thus prevents tissue destruction.

Gentamicin Sulphate:

Gentamicin is a bactericidal antibiotic which acts by inhibiting protein synthesis.

Gentamicin sulfate is a water-soluble antibiotic of the aminoglycoside group which has shown activity against a wide variety of pathogenic gram-negative and gram-positive bacteria.

5.2 Pharmacokinetic properties

Econazole Nitrate:

Absorption: It is minimally absorbed after topical application.

Triamcinolone Acetonide:

Absorption: Triamcinolone acetonide is absorbed after topical application. Distribution: It is distributed mainly in protein bound form. Metabolism: It is metabolized primarily in the liver.

Excretion: It is excreted by the kidneys and small amount is excreted through bile also

Gentamicin Sulphate:

Topical application of gentamicin can result in some systemic absorption. Treatment of large areas can result in plasma concentrations of up to 1 μ g/ml.

> 90% Gentamicin is excreted in the urine by glomerular filtration.

< 10% is bound to plasma protein.

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$T_{1/2}$ = 2 - 3 hours in individuals with normal kidney function but can be increased in cases of renal insufficiency.

5.3 Pre-clinical Safety:

Nil

6. Pharmaceutical Particulars:

6.1 List of Excipients:

Cetamacrogal 1000	BP
Cetostery Alcohol	BP
White Soft Paraffin	BP
Propylene Glycol	BP
Liquid Paraffin	BP
Methyl Paraben	BP
Purified water	BP

6.2 Incompatibilities: Nil

6.3 Shelf Life: 36 months.

6.4 Special Precautions for storage:

Store below 30°C. Keep away from direct Sunlight.
Keep out of reach of children.

6.5 Nature and contents of container:

White coloured homogenous cream s filled in 20 g Aluminium tube with white lid and packed in a carton along with pack insert.

6.6 Special precautions for disposal and other handling:

No special requirements.

7. Marketing Authorization Holder: LESANTO LABORATORIES.

8. Marketing Authorization Number: ---

9. Date of first Authorization /renewal of the authorization: ---

10. Date of revision of text: March 2018