

SUMMARY OF PRODUCT CHARACTERISTICS

**PRODUCT NAME: BACTAGON – Econazole Nitrate,
Triamcinolone Acetonide and Gentamicin Cream**

DOSAGE FORM: Semi-Solid Dosage Form – Cream

THERAPEUTIC CATEGORY – Antifungal, Antibiotic, Anti-inflammatory, Anti-pruritic and Anti bacterial.

COMPOSITION

Econazole Nitrate BP.....1% w/w
Triamcinolone Acetonide BP.....0.1% w/w
Gentamicin Sulfate BP equivalent to Gentamicin.....0.1% w/w
In a cream base.....q.s.

EXCIPIENTS:

Chlorocresol, Cetomacrogol-1000, Cetostearyl Alcohol, Light Liquid Paraffin, White Soft Paraffin, Sodium Dihydrogen Phosphate Dihydrate, Disodium Hydrogen Phosphate (Dihydrate), Disodium Edetate, Sodium Metabisulfite, Propylene Glycol, Purified Water.

PHARMACOLOGY

Pharmacodynamics

Econazole is an antifungal medication related to fluconazole (Diflucan), ketoconazole (Nizoral), itraconazole (Sporanox), and clotrimazole (Lotrimin, Mycelex). Econazole prevents fungal organisms from producing vital substances required for growth and function. This medication is effective only for infections caused by fungal organisms. It will not work for bacterial or viral infections.

Triamcinolone and its derivatives are synthetic glucocorticoids that are used for their anti-inflammatory or immunosuppressive properties.

Gentamicin is a broad spectrum aminoglycoside antibiotic. Aminoglycosides work by binding to the bacterial 30S ribosomal subunit, causing misreading of t-RNA, leaving the bacterium unable to synthesize proteins vital to its growth. Aminoglycosides are useful primarily in infections involving aerobic, Gram-negative bacteria, such as Pseudomonas, Acinetobacter, and Enterobacter. In addition, some mycobacteria, including the bacteria that cause tuberculosis, are susceptible to aminoglycosides. Infections caused by Gram-positive bacteria can also be treated with aminoglycosides, but other types of antibiotics are more potent and less damaging to the host. In the past the aminoglycosides have been used in conjunction with penicillin-related antibiotics in

streptococcal infections for their synergistic effects, particularly in endocarditis. Aminoglycosides are mostly ineffective against anaerobic bacteria, fungi and viruses.

Pharmacokinetics

Econazole nitrate: Econazole interacts with 14- α demethylase, a cytochrome P-450 enzyme necessary to convert lanosterol to ergosterol. As ergosterol is an essential component of the fungal cell membrane, inhibition of its synthesis results in increased cellular permeability causing leakage of cellular contents. Econazole may also inhibit endogenous respiration, interact with membrane phospholipids, inhibit the transformation of yeasts to mycelial forms, inhibit purine uptake, and impair triglyceride and/or phospholipid biosynthesis. After topical application to the skin of normal subjects, systemic absorption of Econazole nitrate is extremely low. Although most of the applied drug remains on the skin surface, drug concentrations were found in the stratum corneum which, by far, exceeded the minimum inhibitory concentration for dermatophytes.

Triamcinolone nitrate: The anti-inflammatory actions of corticosteroids are thought to involve lipocortins, phospholipase A2 inhibitory proteins which, through inhibition of arachidonic acid, control the biosynthesis of prostaglandins and leukotrienes. The immune system is suppressed by corticosteroids due to a decrease in the function of the lymphatic system, a reduction in immunoglobulin and complement concentrations, the precipitation of lymphocytopenia, and interference with antigen-antibody binding. Rapid absorption following oral administration.

Gentamicin: Aminoglycosides like gentamicin "irreversibly" bind to specific 30S-subunit proteins and 16S rRNA. Specifically gentamicin binds to four nucleotides of 16S rRNA and a single amino acid of protein S12. This interferes with decoding site in the vicinity of nucleotide 1400 in 16S rRNA of 30S subunit. This region interacts with the wobble base in the anticodon of tRNA. This leads to interference with the initiation complex, misreading of mRNA so incorrect amino acids are inserted into the polypeptide leading to nonfunctional or toxic peptides and the breakup of polysomes into nonfunctional monosomes. Injections lead to peak serum concentrations in 30-60 minutes.

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. Gentamicin is absorbed in small quantities following topical application to the eye. Gentamicin is also absorbed in small amounts following topical application to the ear (especially if the eardrum is perforated or if tissue damage is present).

INDICATIONS

For topical treatment of antiinflammatory and other dermatomycoses caused by fungi and bacteria:

- vulvovaginal candidiasis, trichomonas, vaginitis, Trichophytosis (tinea corporis, tinea face, tinea capitis etc),
- Trychophytosis (tinea corporis, tinea pedis etc)
- Contact dermatitis,eczema, impetigo etc

Bacterial skin infections caused by susceptible strains of gentamicin.

CONTRAINDICATIONS

- Patients with hypersensitivity to any of the components of Econazole Nitrate, Triamcinolone Acetonide and Gentamicin Cream.
- Patients with tuberculosis, varicella, herpes simplex, herpes zoster, vaccinia and syphilis.
- Patients with eczematous otitis externa and perforated eardrum.

PRECAUTIONS

Hypersensitivity has rarely been recorded. If it occurs, application of the product should be discontinued. The infected area should be kept clean and dry during treatment.

Pregnancy and lactation

Pregnancy:

Not the Econazole but the Triamcinolone Acetonide crosses the placenta and topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development. The relevance of this finding to human beings has not been established. However, topical steroids in large amounts or for prolonged periods should not be used in pregnancy.

Lactation:

Negligible amount of econazole and to some extent Triamcinolone may be excreted in small amounts in breast milk. So, this cream should not be prescribed to the lactating mother or if prescribed lactation should be withheld during treatment.

INTERACTIONS WITH OTHER MEDICINES

Not Applicable

ADVERSE EFFECTS

Rarely, transient local mild irritation, itching & redness may occur immediately after application. Econazole has minimal allergenic effect and is well tolerated, even by delicate skin. Adrenal suppression on long term continuous topical steroid therapy may occur, particularly in infants or children, or when occlusive dressings are applied. It should be noted that an infant's napkin may act as an occlusive dressing.

DOSAGE AND ADMINISTRATION

Apply 2-3 times daily to the affected areas and rubbed gently.

OR

As directed by the physician.

SYMPTOMS AND TREATMENT OF OVERDOSAGE

Econazole Nitrate, Triamcinolone Acetonide & Gentamicin Cream is intended for topical use. If accidental ingestion of large quantities of the product occurs, an appropriate method of gastric emptying may be used if considered desirable.

STORAGE

Do not store above 30°C. Protect from light.

Do not freeze. Do not accept if the seal is broken.

Puncture nozzle seal of the tube with piercing point of cap.

Keep the tube tightly closed after use.

Keep the medicine out of reach of children.

PRESENTATION

30g in Collapsible Aluminium tube. 1 such tube in a printed carton with a printed insert.

Manufactured by:

 **S Kant**
HEALTHCARE Ltd.

1802-1805, G.I.D.C., Phase III,

Vapi - 396 195. Gujarat, INDIA.