B-MYCIN EYE & EAR DROPS

Ingredient(s):
Each ml contains:
Gentamicin (as Gentamicin Sulfate) ……..... 3mg
Betamethasone Sodium Phosphate 1mg
Benzalkonium Chloride(as preservative) 0.1mg

Pharmacology (Summary of Pharmacodynamic and Pharmacokinetic):
Pharmacodynamic:
1. This product combines the potent anti-inflammatory and antiallergic action of betamethasone sodium phosphate with the broad-spectrum antibacterial activity of gentamicin sulfate.
2. Betamethasone, a synthetic derivative of prednisolone, offers the advantage over other corticorsteroids of enhanced anti-inflammatory effects with the use of lower dosages.
3. Betamethasone disodium phosphate exerts its topical anti-inflammatory effect in the eye by suppressing cellular and fibrinous exudation and by normalizing the excessive permeability of inflamed capillaries.
4. In-vivo, staphylococcal species have responded favorably to gentamicin sulfate.
5. In-vitro, gentamicin sulfate is active against a wide variety of pathogenic gram-negative and some gram-positive bacteria: Coagulase-positive and coagulase-negative staphylococci, *Escherichia coli*, *Proteus* sp (indole-positive and indole-negative), *Pseudomonas aeruginosa*, species of Klebsiella-Enterobacter-Serratia group, and species of Citrobacter, Salmonella, Shigella, Moraxella, Serratia, and Neisseria particularly the gonococcus.

Pharmacokinetic:
Eye:
Gentamicin may be absorbed in minute quantities following topical application. Betamethasone is absorbed into the aqueous humor, cornea, iris, choroid, ciliary body and retina. Systemic absorption occurs but may be significant only at higher dosages or in extended paediatric therapy.

Ear:
Gentamicin may be absorbed following topical application if the eardrum is perforated or tissue damage is present. There is no relevant information available for betamethasone.

Indication(s):
This product is indicated in the treatment of the following conditions:-

Eye:
1. Corticosteroid-responsive allergic and inflammatory conditions of the palpebral bulbar conjunctiva, cornea and anterior segment of the globe such as conjunctivitis, corneal injuries, superficial punctuate keratitis, vernal keratoconjunctivitis and as an adjunct in the treatment of superficial ocular infections caused by susceptible organisms.
2. Topical treatment of blepharitis, blepharoconjunctivitis, conjunctivitis, dacryocystitis, keratitis, keratoconjunctivitis and acute meibomianitis.

Ear:
1. Allergic otitis externa, infective otitis and other corticosteroid-responsive disorders of the external auditory meatus.
2. Indicated in the treatment of mastoidectomy cavity infections, chronic suppurative otitis media, subacute purulent otitis media with tympanic membrane perforation and external otitis.

Dosage and Administration:
Eye:
Mild to moderate infections: 1 drop to the eye(s) every 4 hours.
Severe infections: 1 drop to the eye(s) every hour.

Ear:
3 or 4 drops to the ear canal 3 times a day, with dosage gradually being decreased as the inflammation subsides.

Mode of Administration:
Ophthalmic and otic

Contraindication(s):
This product is contraindicated in patients with sensitivity to corticosteroids or aminoglycosides and patients with the following conditions:

Eye:
Ocular fungal diseases, acute superficial herpes simplex keratitis or acute infectious viral disease, a history of or active ocular tuberculosis.

Ear:
Bullous myringitis, herpes simplex, herpes zoster oticus, tubercular or fungal infections of the ear, vaccinia, varicella, or other viral disease of the ear, chronic otitis media or perforated eardrum.

Precaution(s) / Warning(s):

1. Eye: This product should be used with care in patients with cataracts or with conditions with predispose to cataract formation (eg. diabetes mellitus). It may also result in perforation if used in patients with diseases which cause thinning of the cornea and sclera. This product may exacerbate chronic, open angle glaucoma and should be used with caution in patients with a family history of glaucoma. There may be a risk of exacerbation or secondary infections in patients with infections of cornea or conjunctiva. Hypersensitivity reactions have been reported following application of this product. Less frequently stinging or burning of the eye may occur.
2. Ear: It should be used with care in patients with acute or chronic ear infection as well as patient with otitis media, especially children.

GENTAMICIN TOPICAL PREPARATIONS
Use of topical gentamicin preparations in closed hospital settings is actively discouraged.

SODIUM METABISULPHITE
This preparation contains Sodium metabisulphite that may cause serious allergic type reactions in certain susceptible patients. Do not use if known to be hypersensitive to bisulphites.

Interaction with Other Medicaments:
Co-treatment with CYP3A inhibitors, including cobicistat-containing products, is expected to increase the risk of systemic side-effects. The combination should be avoided unless the benefit outweighs the increased risk of systemic corticosteroid side-effects, in which case patients should be monitored for systemic corticosteroid side-effects.

Pregnancy and Lactation:
Safety of the use of topical corticosteroid/antibiotic preparations during pregnancy has not been established. This product should not be given to pregnant women unless the potential benefit justifies the potential risk to the fetus.
It is not known whether the components of this product are excreted in human milk. Consideration should be given to discontinue nursing while the product is being used. Caution should be exercised when this product is administered to a nursing woman.

Side Effect(s):
Eye: Frequent or intensive use may retard corneal healing. Some systemic absorption occurs but only at higher dosages or in extended paediatric therapy. The different dose/weight ratio for children increases the risk of adrenal suppression. This product may cause temporary mild blurred vision. Less frequently, burning, stinging, redness or watering of the eyes occurs. Corneal thinning and/or globe perforation, glaucoma, ocular hypertension, optic nerve damage, posterior subcapsular cataract, visual acuity and field defects, and secondary ocular infection have been reported rarely.

Ear: This product may also cause burning and stinging of the ear.

Symptoms and Treatment for Overdosage, and Antidote(s):
Symptoms:

1. Excessive prolonged use of topical corticosteroids can suppress pituitary-adrenal function resulting in secondary adrenal insufficiency and produce manifestations of hypercorticism, including Cushing's disease.
2. A single overdosage of gentamicin would not be expected to produce symptoms.

Treatment:

1. Appropriate symptomatic treatment of corticosteroids overdosage is indicated. Acute hypercorticoid symptoms are virtually reversible. Treat electrolyte imbalance, if necessary. In cases of chronic toxicity, slow withdrawal of corticosteroids is advised.
2. Although a single overdose is not expected to require treatment, gentamicin can be removed from the blood by hemodialysis or peritoneal dialysis. Approximately 80-90% is removed from the circulatory system during 12 hrs of hemodialysis. Peritoneal dialysis appears to be less effective.

Shelf-Life:
2 years from the date of manufacture.
Discard 1 month after opening.

Storage Condition(s):
Store at temperature below 30ºC

Product Description:
A clear and colorless to slightly yellowish solution.

Dosage Forms and Packaging available:
Eye & Ear Drop Solution.
Plastic bottle of 5ml, 5ml x 10, 5ml x 12, 5ml x 20 & 5ml x 24.

Y. S. P.®
Manufacturer and Product Registration Holder:
Y.S.P. INDUSTRIES (M) SDN. BHD. (199001001034)
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