BETAGEN EYE/EAR DROPS

DESCRIPTION

A clear, colorless, sterile solution containing Gentamicin Sulphate eq. to Gentamicin 0.3% w/v, Betamethasone Sodium Phosphate 0.1% w/v and Benzalkonium Chloride (preservative) 0.01% w/v.

INDICATIONS

Betagen eye/ear drops are indicated in the treatment of the following conditions :-

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

Ear : Allergic otitis externa, infective otitis and other corticosteroid-responsive disorders of the external auditory meatus. Betagen eye/ear drops are indicated in the treatment of mastoidectomy cavity infections, chronic suppurative otitis media, subacute purulent otitis media with tympanic membrane perforation and external otitis.

PHARMACODYNAMICS

Gentamicin

Gentamicin is an aminoglycoside which is actively transported across the bacterial cell membrane where it binds to a specific receptor protein on the 30 S subunit of bacterial ribosomes. At this site, it interferes with an initiation complex between mRNA and the 30 S subunit, inhibiting protein synthesis. DNA may be misread, thus producing nonfunctional proteins, polyribosomes are split apart and are unable to synthesize protein.

Betamethasone

Betamethasone diffuses across cell membranes and complex with specific cytoplasmic receptors. These complexes enter the cell nucleus, bind to DNA and stimulate transcription of mRNA and subsequent protein synthesis of enzymes responsible for the anti-inflammatory effects of betamethasone. In high concentrations, betamethasone may exert direct membrane effects. Betamethasone decreases cellular and fibrinous exudation and tissue infiltration, inhibits fibroblastic and collagen-forming activity, retards epithelial regeneration, diminishes postinflammatory neovascularisation, and reduces toward normal levels the excessive permeability of inflamed capillaries.

Benzalkonium

A 0.01% w/v solution is used as a preservative for eye/ear drops.

PHARMACOKINETICS

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.

DOSAGE

Eye : 1 drop to the eye(s) every 4 hours, for mild to moderate infections. 1 drop to the eye(s) every hour for severe infections.

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

SIDE EFFECTS

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. Betagen eye/ear drops may cause temporary mild blurred vision. Less frequently, burning, stinging, redness or watering of the eyes occurs. Corneal thinning and/or globe perforation, glaucoma, occular hypertension, optic nerve damage, posterior subcapsular cataract, visual acuity and field defects, and secondary occular infection have been reported rarely.

Ear : Betagen eye/ear drops may also cause burning or stinging of the ear.

CONTRAINDICATIONS

Betagen eye/ear drops are 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 infections viral disease, a history of or active occular 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.

PRECAUTIONS

Eye : Betagen eye/ear drops should be used with care in patients with cataracts or with conditions which 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. Betagen eye/ear drops 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 infection in patients with infections of the cornea or conjunctiva. Hypersensitivity reactions have been reported following application of Betagen eye/ear drops. Less frequently stinging or burning of the eye may occur.
Ear : It should be used with care in patients with acute or chronic ear infections as well as patients with otitis media, expecially children.

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

DRUG INTERACTIONS

Chronic or intensive use of Betagen eye/ear drops may increase intraoccular pressure and decrease the efficacy of antiglaucoma agents. Intraoccular hypertension in patients predisposed to acute angle closure may be more likely if Betagen eye/ear drops are used in conjunction with anticholinergics, especially atropine and related compounds. The risk of infection is also increased with concurrent use of contact lenses.

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.

OVERDOSAGE

Eye : Acute oral overdose of ophthalmic corticosteroids does not result in serious adverse effects. Dilution with fluids is the mainstay of therapy.
Ear : There is no relevant information available.

TOXICOLOGY

Eye
Gentamicin : Problems involving reproduction, pregnancy and breast-feeding have not been documented in humans. No paediatric and geriatric specific problems have been reported to date.

Betamethasone
Pregnancy/Reproduction : Infants born to mothers who have received substantial doses of corticosteroids should be observed for signs of hypoadrenalism.
(FDA Pregnancy Category - not available for betamethasone)

Breast-feeding : No problems in humans have been documented.

Paediatrics : Betamethasone should be used with caution in children 2 years of age or younger because the different dose/weight ratio for children increases the risk of adrenal suppression. This risk increases with the duration of therapy.

Geriatics : No problems in human have been documented.

Ear
No problems in the categories mentioned above have been reported.

Route of Administration: Eye and Ear

PRESENTATION

5ml x 12 bottles

STORAGE CONDITIONS AND USER INSTRUCTIONS

Keep container tightly closed. Store in a dry place below 25°C.
Protect from sunlight and moisture. Keep out of reach of children.
Jauhkan daripada kanak-kanak.
Shelf Life : Please refer to outer package.
Do not touch tip to any surface.
Discard unused portions after compliance to full therapy.
Do not wear contact lenses during and for a time following application of medicine.
May be instilled directly into ear canal or administered via a saturated gauze or cotton wick gently placed into the canal.

Product Registration Holder & Manufacturer
Duopharma (M) Sdn. Bhd.
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Back, Size: 16cm (W) x 16.1cm (H)