

For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory.

BACTIGEN Eye Drops B.P.

COMPOSITION

Gentamicin 0.3% w/v
(as Gentamicin Sulphate B.P.)
Benzalkonium chloride N.F. 0.01% w/v
(as preservative)
Aqueous Buffered vehicle q.s.

DESCRIPTION

Gentamicin is an aminoglycoside antibiotic obtained from cultures of *Micromonospora purpurea*.

Gentamicin is usually bactericidal in action. The drug inhibits protein synthesis in susceptible bacteria by irreversibly binding to 30S ribosomal subunits.

In general, gentamicin is active against many aerobic gram-negative bacteria and some aerobic gram-positive bacteria.

In vitro, gentamicin concentrations of 1-8 µg/ml inhibit most susceptible strains of *Escherichia coli*, *Haemophilus influenzae*, *Moraxella lacunata*, *Neisseria*, indole-positive and indole-negative *Proteus*, *Pseudomonas* (including most strains of *Pseudomonas aeruginosa*), *Staphylococcus aureus*, *Staphylococcus epidermidis*, and *Serratia*.

Systemic absorption was not detected after topical use. Penetration of antibiotic in various ocular tissues depends on the degree of inflammation, the frequency of application, and the interval between the drops.

INDICATIONS

Gentamicin Eye Drops is indicated in the topical treatment of ocular bacterial infections including conjunctivitis, keratitis, keratoconjunctivitis, corneal ulcers, blepharitis, blepharconjunctivitis, acute meibomianitis, and dacryocystitis, caused by susceptible strains of the following microorganisms: *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Streptococcus pyogenes*, *Streptococcus pneumoniae*, *Enterobacter aerogenes*, *Escherichia coli*, *Haemophilus influenzae*, *Klebsiella pneumoniae*, *Neisseria gonorrhoeae*, *Pseudomonas aeruginosa*, and *Serratia marcescens*.

DOSAGE & ADMINISTRATION

Instill one or two drops into the affected eye(s) every four hours. In severe infections, dosage may be increased to as much as two drops every hour.

CONTRAINDICATIONS

Gentamicin Eye Drops is contraindicated in patients with known hypersensitivity to Gentamicin, any other aminoglycoside antibiotic, or to any other ingredient of the preparation.

PRECAUTIONS

Prolonged use of topical antibiotics may give rise to overgrowth of nonsusceptible organisms, including fungi. Bacterial resistance to gentamicin may also develop. If purulent discharge, inflammation or pain becomes aggravated, the patient should discontinue use of the medication and consult a physician.

If irritation or hypersensitivity to any component of the drug develops, the patient should discontinue use of this preparation, and appropriate therapy should be instituted.

WARNING

Not for injection into the eye.

Gentamicin Eye Drops is not for injection into the eye. They should never be injected subconjunctivally, nor should they be directly introduced into the anterior chamber of the eye. Do not touch the nozzle tip to any surface, since this may contaminate the solution.

ADVERSE REACTIONS

Bacterial and fungal corneal ulcers have developed during treatment with gentamicin ophthalmic preparations.

The most frequently reported adverse reactions are ocular burning and irritation upon drug instillation, non-specific conjunctivitis, conjunctival epithelial defects and conjunctival hyperemia.

Other adverse reactions, which have occurred rarely, are allergic reactions, thrombocytopenic purpura and hallucinations.

DRUG INTERACTIONS

No specific drug interactions have been reported with Gentamicin Eye Drops.

OVERDOSAGE AND TREATMENT OF OVERDOSAGE

No cases of gross accidental overdosage or self-poisoning appear to have occurred.

MODE OF USE



MADE IN INDIA BY

FDC Limited

Regd Office : B-8 M.I.D.C. Waluj, Dist Aurangabad, 431 136

WIT BA SLEX

Size : 110 x 144 mm
Same size A/w
Printed Front & Back
Export artwork - Sri Lanka