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

BACTIGEN EYE DROPS

Gentamicin Eye Drops BP

Description:
A clear colourless solution.

Composition:
Gentamicin..... 0.3% w/v
(3000 Units/ml)
(As Gentamicin Sulphate BP)
Benzalkonium Chloride NF..... 0.01% w/v
(As preservative)

Presentation:
Bactigen Eye drops 0.3% w/v available in 5ml plastic container.

Pharmacodynamics:
Gentamicin is an aminoglycoside antibiotic obtained from cultures of micromonospora pupurea. 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 lcunata, 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.

Pharmacokinetics:
Topical application of gentamicin can result in some systemic absorption. Treatment of large areas can result in plasma concentrations of up to 1µg/ml. > 90% Gentamicin is excreted in the urine by glomerular filtration. < 10% is bound to plasma protein. T½ = 2 - 3 hours in individuals with normal kidney function, but can be increased in cases of renal insufficiency.

Indication:
BACTIGEN is indicated in the topical treatment of infections caused by susceptible bacteria of the external structures of the eyes and their adnexa, such as conjunctivitis, keratitis and keratoconjunctivitis, corneal ulcers, blepharitis and blepharoconjunctivitis, acute meibomianitis and dacryocystitis.

Recommanded Dose:
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.

Mode Of Administration:
For Eye Administration only.

Contraindication:
Gentamicin eye drops is contraindicated in patients with known hypersensitivity to Gentamicin. Any other aminoglycoside antibiotic or to any other ingredient of the prepartation.

Warning and Precautions: Precautions:
Prolonged use of topical antibiotics may give rise to overgrowth of non susceptible organisms, including fungi. Bacterial resistances to gentamicin may also develop. If purulent discharge inflammation or plain 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 subconcjunctivally, 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.

Interactions With Other Medicaments:
Concurrent use with other potentially nephroxtoxic or ototoxic drugs should be avoided unless considered essential by the physician.

Pregnancy and Lactation:
Safety for use in pregnancy and lactation has not been established. Gentamicin should only be used in pregnancy or lactation when considered essential by the physician, after careful assessment of the potential risks and benefits.

Side Effects:
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 conjucntival hyperernia. Other adverse reactions, which have occurred rarely are allergic reactions,thromobocytopenic purpura and hallucinations.

Symptoms And Treatment of Overdose:
No cases of gross accidental over dosage or self-poisoning appear to have occurred.

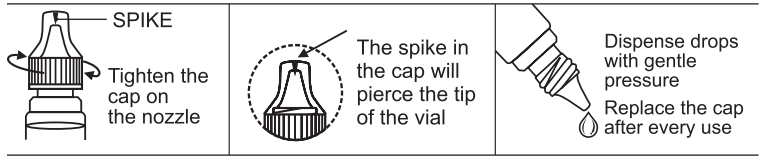
Storage Condition:
Store in dry place, below 30°C and protect from light.

Shelf Life:
24 Months from the Date of Manufacture.

Therapeutical Code:
J01GB03 -GENTAMICIN.

MAL06091353AZ
BRU15011727P

MODE OF USE



Manufactured in India by:
FDC Limited
B-8, MIDC Industrial Area, Waluj,
Chhatrapati Sambhajinagar - 431 136,
Maharashtra.

Product registration holder and imported by:
Unimed Sdn. Bhd.
No. 53, Jalan Tembaga SD 5/2B.
Bandar Sri Damansara 52200,
Kuala Lumpur, Malaysia.

2000016473

FDC Limited	LEAFLET
Mini Pharma Code No.:	Front: 2948 / Back: 2949
Size	110mm x 144mm - Artwork Same Size
Folded Size	Unfolded Size
No. of Folds	
GSM	60 GSM
Paper	Maplitho Paper
Specifican No.	
Colour	■ TEXT IN BLACK
SAP Code: 2000016473	Supercedes SAP Code: 2000005289
Location : Waluj - Country : Malaysia	Prepared On : 03-05-2025

Reason for Change:
1. FDC address changed from Aurangabad to Chhatrapati Sambhajinagar.
2.Product registration holder added
3. Brand name, Generic name & Label claim updated as per licence copy
4. BRU No. and MAL No. added.