hovid Gentamicin Eye Drops 0.3% w/v

VIGEN03-M3

DESCRIPTION
A pale yellow clear solution.

COMPOSITION
Gentamicin Sulfate equivalent to Gentamicin 0.3% w/v

ACTIONS AND PHARMACOLOGY
Gentamicin is a mixture of antibiotic substances produced by the growth of micromonospora purpurea. It is bactericidal with greater antibacterial activity than streptomycin, neomycin or kanamycin.

Gentamicin exerts a number of effects on cells of susceptible bacteria. It affects the integrity of the plasma membrane and the metabolism of RNA, but it's most important effect is inhibition of protein synthesis at the level of the 30s ribosomal subunit.

PHARMACOKINETICS
Gentamicin is not readily absorbed from the gastro-intestinal tract. Gentamicin is 70-85% bound to plasma albumin following administration and is excreted 90% unchanged in urine. The half-life for its elimination in normal patients is 2 to 3 hours.

Effective plasma concentration is 4 - 8ug/ml.
The volume of distribution (V_D) is 0.31/kg.
The elimination rate constant is 0.02 Hr^{-1} for anuric patients*; 0.30 Hr^{-1} for normal patients.

*Therefore in those with anuria care must be exercised.

INDICATIONS
hovid Gentamicin Eye Drops 0.3% w/v are indicated in the treatment of the following : Blepharitis, blepharoconjunctivitis, conjunctivitis, dacryocystitis, keratitis, keratoconjunctivitis and acute meibomianitis caused by coagulase-negative and positive *Staphylococci*, *Pseudomonas aeruginosa* indole-positive and negative *Proteus* species. *Escherichia coli*, *Klebsiella pneumoniae*, *Haemophilus influenzae*, *Haemophilus aegyptius*, *Enterobacter aerogenes*, *Moraxella lacunata* and *Neisseria* species.

CONTRAINDICATIONS
Should not be administered to patients with a known allergy to gentamicin and other aminoglycosides.

Evidence exists that gentamicin may cause neuromuscular blockade and is therefore contra-indicated in myasthenia gravis and related conditions.

WARNINGS AND PRECAUTIONS
Avoid prolonged use. Prolonged use may lead to skin sensitisation and the emergence of resistant organisms. Cross-sensitivity with other aminoglycoside antibiotics may occur.

In severe infections, topical use of gentamicin should be supplemented with appropriate systemic antibiotic treatment.

Not for use with contact lenses.

PREGNANCY AND LACTATION
There are no proven cases of intrauterine damage caused by gentamicin. However, in common with most drugs known to cross the placenta, usage in pregnancy should only be considered in life-threatening situations where expected benefits outweigh possible risks. In the absence of gastrointestinal inflammation the amount of gentamicin ingested from the milk is unlikely to result in significant blood levels in breast-fed infants.

DRUG INTERACTIONS
Neuromuscular blockade and respiratory paralysis have been reported in patients from the administration of aminoglycosides to patients who have received curare-type muscle relaxants during anaesthesia.

MAIN SIDE/ADVERSE EFFECTS
Eye Disorders:
Local sensitivity, blurred vision, eye irritation, burning sensation, stinging sensation, itching (eye pruritus)

Skin & Subcutaneous tissue Disorders:
Burning sensation, stinging, itching (pruritus), dermatitis.

In the event of irritation, sensitivity or super-infection, treatment should be discontinued and appropriate therapy instituted.

OVERDOSE AND TREATMENT
Haemodialysis and peritoneal dialysis will aid the removal from blood but the former is probably more efficient. Calcium salts given intravenously have been used to counter the neuromuscular blockade caused by gentamicin.

DOSAGE AND ADMINISTRATION
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.

INCOMPATABILITIES
Pharmaceutically incompatible with amphotericin, cephalosporins, erythromicin, heparin, penicillins, sodium bicarbonate and sulphadiazine sodium.

Note: The information given here is limited. For further information, consult your doctor or pharmacist.

Storage:
Store below 30°C. Protect from light.
It is recommended to discard remaining contents one month after opening

Presentation/Packing:
Eye Drops of 5mL, 1 bottle per box.

Product Registration Holder / Repacked by:
HOVID Bhd.
121, Jalan Tunku Abdul Rahman,
30010 Ipoh, Malaysia.
Manufactured by: Amanta Healthcare Limited
(formerly Marck Biosciences Ltd.)
Plot No. 876, N.H. No. 8, Hariyala, Matar, Gujarat, India.

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