SUMMARY OF PRODUCT CHARACTERISTICS

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" For the use of registered medical practitioner or Hospital only"

GXACIN

Gentamicin Sulfate Ophthalmic Solution USP

1. Composition

Each mL contains:
Gentamicin Sulfate USP
E. q. to Gentamicin……..….....0.3%w/v
Benzalkonium Chloride Solution BP…..0.02%v/v
(As preservative)
Sterile aqueous vehicle.……q.s

2. Dosage form

Ophthalmic Solution

3. Indications and Usage

Treatment of infections of the external structures of the eye and its adnexa caused by susceptible bacteria. Such infections include conjunctivitis, keratitis, kerato-conjunctivitis, corneal ulcers, blepharitis and blepharo-conjunctivitis, acute meibomianitis, episcleritis and dacryocystitis. It may be used for the prevention of ocular infection after: removal of a foreign body, burns or lacerations of the conjunctiva; damage from chemical or physical agents and after ocular surgery.

4. Clinical Pharmacology:

Pharmacodynamic Properties:

Pharmacotherapeutic group: Antibiotic, ATC Code: S01AA11
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.

Pharmacokinetic properties:
Topical application of Gentamicin can result in some systemic absorption. Treatment of large areas can result in plasma concentrations of up to 1µg/ml. Gentamicin is not readily absorbed from the gastro-intestinal tract < 10% is bound to plasma protein.following administration and is excreted >90% in the urine by glomerular filtration. The half-life for its elimination in normal patients is 2 to 3 hours, but can be increased in cases of renal insufficiency. Effective plasma concentration is 4 - 8ug/ml
The volume of distribution (VD) is 0.3 1/kg

5. Dosage and Administration

Adults, including the elderly and children:
Instill 1-2 drops into the affected eye up to six times a day, or more frequently if required. (severe infections may require 1 or 2 drops every fifteen to twenty minutes initially, reducing the frequency of instillation gradually as the infection is controlled).

6. Contraindication

Hypersensitivity to active substance, Gentamicin or to any of the excipient. 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.

7. 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.
This formulation of Gentamicin ophthalmic solution contains benzalkonium chloride as a preservative which may be deposited in soft contact lenses. Hence, Gentamicin should not be used while wearing these lenses. The lenses should be removed before instillation of the drops and not reinserted earlier than 15 minutes after use.

Back

Benzalkonium chloride has been reported to cause eye irritation, symptoms of dry eyes and may affect the tear film and corneal surface. Should be used with caution in dry eye patients and in patients where the cornea may be compromised. Patients should be monitored in case of prolonged use.
Serious adverse reactions including neurotoxicity, ototoxicity and nephrotoxicity have occurred in patients receiving systemic gentamicin therapy.

8. Adverse Reaction
There are no modern clinical studies available that can be used to determine the frequency of undesirable effects. Therefore, all the undesirable effects listed are classed as "frequency unknown".
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.
Renal & Urinary Disorders:-
Gentamicin may cause nephrotoxicity when given systemically. However, it is likely that systemic absorption following topical administration does not constitute a comparable risk.
In the event of irritation, sensitivity or super-infection, treatment should be discontinued and appropriate therapy instituted.

9. Drug Interaction
Potent diuretics such as ethacrynic acid and frusemide are believed to enhance any risk of ototoxicity whilst amphotericin B, cisplatin and cyclosporin and cephalosporins are potential enhancers of nephrotoxicity.
Concurrent use with other potentially nephrotoxic or ototoxic drugs should be avoided unless considered essential by the physician.
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.

10. Fertility, 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.

11. Overdose
Hemodialysis 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.

12. Description: Clear colourless solution

13.Storage: Do not store above 30ºC. Protect from light. Do not refrigerate or freeze

14. Presentation: 10mL LDPE vial packed in unit carton along with pack insert.

"Use the solution within one month after opening the vial".

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