National Agency for Food & Drug Administration & Control (NAFDAC)

Registration & Regulatory Affairs (R & R) Directorate

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)
GENTAMYCIN EYE/EAR DROP

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. NAME OF THE MEDICINAL PRODUCT

Gentamicin Eye/Ear Drops 0.3%w/v

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Gentamicin sulphate equivalent to 30mg gentamicin in 10ml of solution

For a full list of excipients, see Section 6.1.

3. PHARMACEUTICAL form

Eye/Ear drops

4. Clinical particulars

4.1 Therapeutic indications

Gentamicin Eye/Ear drops are indicated:

- For the treatment of superficial eye and ear infections caused by organisms sensitive to gentamicin. Such infections include conjunctivitis, keratitis, kerato-conjunctivitis, corneal ulcers, blepharitis and blepharo-conjunctivitis, acute meibomianitis, episcleritis and dacryocystitis
- For prophylaxis against infection in trauma or the eye or ear.

4.2 Posology and method of administration

Adults, including the elderly and children

Eyes: 1 or 2 drops should be instilled in the affected eye up to six times a day, or more frequently if required. (severe infections may require 1 or 2 drops every 15 to 20 minutes initially, reducing the frequency of installation gradually as the infection is controlled)

Ears: The areas should be cleaned, and 2-3 drops instilled in the affected ear 3 to 4 times a day and at night, or more frequently if required.

4.3 Contraindications

Hypersensitivity to the gentamicin or other aminoglycosides. 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.

Perforated tympanic membrane

4.4 Special warnings and precautions for use

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.

Gentamicin may cause ototoxicity (vestibular damage; irreversible partial or total deafness) when given systemically or when applied topically to open wounds or damaged skin. This effect is dose-related and is enhanced by renal and/or hepatic impairment and is more likely in the elderly.

Topical application of gentamicin into the middle ear also carries a theoretical risk of ototoxicity in susceptible patients.

Concurrent use with other potentially nephrotoxic or ototoxic drugs should be avoided unless considered essential by the physician (see section 4.5).

Not for use with contact lenses

4.5 Interaction with other medicinal products and other forms of 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.

4.6 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.

4.7 Effects on ability to drive and use machines

Patients should be advised that the use of gentamicin in the eye may cause transient blurring of vision. If affected, patients should not drive or operate machinery until vision has cleared.

4.8 Undesirable effects

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)

Ear & Labyrinth Disorders:-

Local sensitivity; ototoxicity; vestibular disorder; hearing loss

Skin & Subcutaneous tissue Disorders:-

burning sensation, stinging, itching (pruritus); dermatitis.

Renal & Urinary Disorders:-

Nephrotoxicity; acute renal failure

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

4.9 Overdose

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.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code: J01GB03
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.

5.2 Pharmacokinetic properties

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 0.3 1/kg

The elimination rate constant is;

0.02 Hr^{-1} for anuric patients*

0.30 Hr^{-1} normal

* Therefore, in those with anuria care must be exercised.

5.3 Preclinical safety data

Nothing of relevance which is not included in other sections of the SPC

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Benzalkonium Chloride
- Disodium Hydrogen phosphate (Di hydrate)
- Sodium Dihydrogen phosphate (Di hydrate)
- Sodium chloride
- Sodium Hydroxide

6.2 Incompatibilities

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

6.3 Shelf life

Unopened: 24months

Opened: 28 days

6.4 Special precautions for storage

Store below 30°C

Protect from light

6.5 Nature and contents of container

10ml low density polyethylene bottle.

6.6 Special precautions for disposal and other handling

Do not touch the dropper tip to any surface as this may contaminate the solution

Close the bottle immediately after use.

Any unused product or waste material should be disposed of in accordance with local requirements.

7. APPLICANT/SUPPLIER

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