SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Gentamicin Eye/Ear Drops 0.3% W/V

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredient

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

Excipient(s) with known effect:
Benzalkonium chloride 0.10mg/ml
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye/Ear Drops Solution

4 CLINICAL PARTICULARS

4.1. Therapeutic Indications

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.

Also indicated for the treatment of otitis externa.

4.2 Posology and method of administration

Posology

Adults, including the elderly and children

Eyes: 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).

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

4.3 Contra-indications

Hypersensitivity to active substance, Gentamicin or to any of the excipient listed in section 6.1.

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.

There have been observed cases of an increased risk of ototoxicity with aminoglycosides administered to patients with mitochondrial mutations, particularly the m.1555A>G mutation, including cases where the patient's aminoglycoside serum levels were within the recommended range. Some cases were associated with a maternal history of deafness and/or mitochondrial mutation. Mitochondrial mutations are rare, and the penetrance of this observed effect is unknown.

The condition of the ear drum must always be checked before this medicinal product is prescribed. The medicinal product must not be used if the integrity of the ear drum cannot be guaranteed.

Irreversible toxic effects may result from direct contact of gentamicin with the middle and inner ear. The benefits of gentamicin therapy should be considered against the risk of infection itself causing hearing loss.

This formulation of Gentamicin Eye/Ear Drops 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.

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. Although these effects have not been reported following topical otic use of gentamicin, caution is advised when used concomitantly with systemic aminoglycosides.

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

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.

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:-
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.

Reporting of suspected adverse reactions:-
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via Yellow card scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

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

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 ($^{V}_{D}$) is 0.3 1/kg

5.3. Pre-clinical Safety Data

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Chloride
Disodium Edetate
Sodium Metabisulphite
Borax
Benzalkonium Chloride solution
Water for Injection

Sodium Hydroxide soluion (pH adjuster)
Hydrochloric acid (pH adjuster)

6.2 Incompatibilities
None known.

6.3 Shelf life

Unopened: 24 months
Opened: 28 days

6.4. Special Precautions for Storage

Protect from light.
Store below 25°C

6.5 Nature and contents of container

10ml low density polyethylene bottle with polystyrene spiked cap.

6.6 Special precautions for disposal and other handling
Not applicable.

7 MARKETING AUTHORISATION HOLDER

FDC International Ltd
Unit 6, Fulcrum 1
Solent Way, Whiteley
Fareham
Hampshire, PO15 7FE.
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 15872/0004

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

22 January 1998/ 18 March 2003

10 DATE OF REVISION OF THE TEXT

16/11/2020