SUMMARY PRODUCT CHARACTERISTICS (SPC)

GENTAMICIN EYE/EAR DROPS (Ivygentacin eye/ear drops)

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1. NAME OF MEDICINAL PRODUCT:

GENTAMICIN EYE/EAR DROPS (Ivygentacin eye/ear drops)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Qualitative composition:

I: Gentamicin sulphate B.P

Quantitative composition:

Gentamicin (as gentamicin sulphate) 0.3%$^{w}/_{v}$. 3 mg/ml

For full list of Excipients, see section 6.1

3. PHARMACEUTICAL FORM OF THE DRUG PRODUCT

EYE/EAR DROP
5ml and 10ml Clear colourless to yellow solution

4. CLINICAL PARTICULARS

4.1 INDICATIONS

For the treatment 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 treatment of otitis externa

4.2 Posology and method of administration:

EYE: Instill 1-2 drops into to the affected eye every four hours as required.

EARS: The area should be cleansed and 2-4 drops instilled 3-4 times daily.

4.3 Contraindications:

Should not be administered to patients with a known allergy to gentamicin or any of the ingredients, or other aminoglycosides. Evidence exists that gentamicin may cause neuromuscular blockade and is therefore contra-indicated in myasthenia gravis and related conditions.
Perforation of the ear drum.

4.4 Special warnings and pre cautions for use:

The condition of the ear drum must always be checked before this medicinal product is prescribed.

Avoid prolonged use. Prolonged use may lead to skin sensitization 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.

Irreversible toxic effects may result from direct contact of gentamicin with the middle and inner ear. This medicinal product must not be used if the integrity of the ear drum cannot be guaranteed.

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. Not for use with contact lenses.

4.5 Interactions with other medicinal products and other forms of interactions

Potent diuretics such as ethacrynic acid and furosemide are believed to enhance any risk of ototoxicity whilst amphotericin B, cisplatin and cyclosporine and cephalosporin 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 Disorder:-
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.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Gentamicin is a mixture of antibiotic substance produced by the growth of micromonospora purpurae. 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 for distribution ($^{V}_{D}$) is 0.3 l/kg

The elimination rate constant is;
$0.02Hr^{-1}$ for anuric patients*
$0.03Hr^{-1}$ normal
*Therefore in those with anuria care must be exercised.

5.3 Pre-clinical safety data

Pre-clinical safety data does not add anything of further significance to the prescriber.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Name of ingredient	**Reference**	**Amount per ml 10 ml**	**Function/Reason For inclusion.**
Disodium edetate	BP	10mg	Chelating agent
Sodium metabisulphite	BP	50mg	Antioxidant agent
Sodium phosphate monobasic	BP	31.2mg	Buffering agent
Sodium phosphate dibasic	BP	334mg	Buffering agent
Sodium chloride	BP	9mg	Tonicity adjusting agent
Benzalkonium chloride	BP	1mg	Microbial preservative
Water for injection	BP	Quantity Sufficient to volume	Solvent

6.2 Incompatibilities None

6.3 Shelf life:

Unopened shelf-life is 24 months.

Opened shelf-life 28 days.

But the patient is advised to discard any remaining drops after the prescribed course of treatment.

6.4 Special precautions for storage:

Store in a cool place (below 25° C) away from light. Keep out of reach of children

6.5 Nature and contents of container:

5ml and 10ml low density polyethylene bottles with a polypropylene spiked cap.

6.6 Special precautions for use and disposal:

No special requirement

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER

9. DATE OF FIRST REGISTRATION/ RENEWAL OF REGISTRATION

10. DATE OF REVISION OF TEXT

25/11/2020

11 DOSIMETRY (IF APPLICABLE) Not Applicable

12 INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUICALS (IF APPLICABLE) Not applicable