Summary of Product Characteristics (SmPC)

1. Name of the medicinal product

Gentamicin eye/ear drops 0.3% 10ml

2. Qualitative and quantitative composition

Each 10ml contains: Gentamicin Sulfate Equivalent to 30mg gentamicin.

3. Pharmaceutical form

Eye/ear drops

A clear, colorless to slightly yellow liquid.

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

Eye: Instill 1-2 drops into 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 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 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.

4.8 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

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 (VD) 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

Sodium bisulfite

Sodium chloride

Anhydrous sodium dihydrogen phosphate

Anhydrous disodium hydrogen phosphate

Ethylparaben

Water for injection

6.2 Incompatibilities

None known

6.3 Shelf life

Three years.

6.4 Special precautions for storage

Store in a cool and dry place below 30°C.Protect from light.

Keep out of the reach of children.

6.5 Nature and contents of container

10ml LDPE bottle

7. APPLICANT/MANUFACTURER

Applicant name: DANNYFAITH PHARMACY LIMITED.
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