SUMMARY OF PRODUCT CHARACTERISTICS

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1. NAME OF THE MEDICINAL PRODUCT

GENTAMICIN/COOPER, 0.3% w/v, eye drops, solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of solution contains Gentamicin Sulfate equivalent to 3 mg Gentamicin.
Excipient with known effect:
Each ml of solution contains 0.1 mg benzalkonium chloride (see section 4.4).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Eye drops, solution

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

GENTAMICIN/COOPER eye drops, solution is indicated for the local 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.

4.2. Posology and method of administration

Posology

Adults, including the elderly and children

Instill 1-2 drops into the affected eye up to six times daily, 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).

4.3. Contraindications

Hypersensitivity to the active substance or to any of the excipients 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 contraindicated in myasthenia gravis and related conditions.

4.4. Special warnings and precautions for use

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.

GENTAMICIN/COOPER contains benzalkonium chloride as a preservative which may be deposited in soft contact lenses. Hence, GENTAMICIN/COOPER should not be used while wearing contact 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 use of gentamicin, caution is advised when used concomitantly with systemic aminoglycosides.

4.5. Interactions 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 cyclosporine 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 aminoglycoside to patients who have received curare-type muscle relaxants during anaesthesia.

4.6. 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.

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)

Skin & Subcutaneous tissue Disorders:
Burning sensation, stinging, itching (pruritus), dermatitis.

Renal & Urinary Disorders:
Gentamicin may cause nephrotoxicity when administered 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 side effects
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 the national reporting system.

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/COOPER can result to some systemic absorption. Treatment of large areas can result in plasma concentrations up to 1 μg/ml.

Gentamicin is not readily absorbed from the gastro-intestinal tract. Less than 10% is bound to plasma proteins following administration and more than 90% is excreted in the urine by glomerular filtration. The half-life for the elimination of gentamicin in in normal patients is 2-3 hours, but can be increased in cases of renal insufficiency.

Effective plasma concentration is 4-8 μg/ml
The volume of distribution (V_D) is 0.3 L/kg.

5.3. Preclinical safety data

Nothing of relevance which is not included in other sections of theSPC.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Benzalkonium Chloride, Edetate Disodium, Sodium Chloride, Sodium Dihydrogen Phosphate Dihydrate, Disodium Phosphate Anhydrous, Water for Injections.

6.2. Incompatibilities

None known.

6.3. Shelf Life

Shelf-life of the ready-to-use product is 36 months.
Shelf-life after opening the package is 28 days.

6.4. Special precautions for storage

Do not store above 30°C.

6.5. Nature and contents of container

GENTAMICIN/COOPER is an ophthalmic solution contained in a 5 ml LDPE white bottle, white LDPE dropper and HDPE-LDPE screw cap.

6.6. Special precautions for disposal

Not applicable.

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER

80345/06-09-2021

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorization: 29-11-1991
Date of last renewal: 06-02-2007

10. DATE OF REVISION OF THE TEXT

06 September 2021