Summary of Product Characteristics

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1. NAME OF THE MEDICINAL PRODUCT

BACTIGEN Eye / Ear Drops (Gentamicin Eye Drops BP)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Gentamicin ……...…….. 0.3 % w/v (3000 units/ml)
(As Gentamicin Sulphate)
Benzalkonium Chloride …… 0.01 % w/v
(As preservative)

3. PHARMACEUTICAL FORM

Opthalmic Solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

BACTIGEN Eye/Ear Drops are indicated in adults and children:
1. For the topical treatment of ocular bacterial infections (such as conjunctivitis, keratitis, keratoconjunctivitis, corneal ulcers, blepharitis, blepharoconjunctivitis, acute meibomianitis, and dacryocystitis) caused by gentamicin susceptible strains.
2. For the treatment of otitis externa.
3. For prophylaxis therapy in case of trauma of the eye or ear.

4.2 Posology and method of administration

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 morefrequently if required. Or, as directed by the physician.

Method of Administration

For auricular/otic and/or ocular use.
Not for injection.
Do not touch tip of the vial to finger or to any other surface since this may contaminate the solution.
Keep the bottle tightly closed when not in use.
If eye irritation occurs, discontinue the use and consult the Physician.
Contact lenses should be removed before instillation of the eye drops and may be reinserted after 15 minutes.
If more than one topical ophthalmic medicinal product is being used, the medicinal products should be instilled 5 to 15 minutes apart. Eye ointments should be administered last.
Discard unused portion, if any, after 28 days of first opening the vial (even though expiry date is longer).
Follow the directions mentioned on the container label

4.3 Contraindications

BACTIGEN Eye/Ear Drops are contraindicated in the following:

1. Hypersensitivity to Gentamicin or to other aminoglycosides or to any of the excipient listed in section 6.1.
2. Myasthenia gravis.
3. Known or suspected perforation of the ear drum.

4.4 Special warnings and precautions for use

Long-term continuous topical therapy should be avoided. 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 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.
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.
Contact lenses should be removed during the period of treatment of ocular infections.
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.
There have been observed cases of an increased risk of ototoxicity with aminoglycosides administered to patients with mitochondrial mutations 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.
This medicine contains benzalkonium chloride and may cause skin reactions, eye irritation and discolour soft contact lenses.
Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. Contact lenses should be removed before using this medicine and put back 15 minutes afterwards. From the limited data available, there is no difference in the adverse event profile in children compared to adults.
Generally, however, eyes in children show a stronger reaction for a given stimulus than the adult eye. Irritation may have an effect on treatment adherence in children. 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.

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 whilstamphotericin 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 Fertility, pregnancy and lactation

Pregnancy

Safety for use in pregnancy has not been established. Gentamicin should only be used in pregnancy when considered essential by the physician, after careful assessment of the potential risks and benefits.

Lactation

Safety for use in lactation has not been established. 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. Gentamicin should only be used in lactation when considered essential by the physician, after careful assessment of the potential risks and benefits.

Fertility

Studies have not been performed to evaluate the effect of topical administration of gentamicin on human fertility.

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 “not known”.

Eye Disorders: Local sensitivity; blurred vision, eye irritation, burning sensation, stinging sensation, itching (eye pruritus).
Ear and Labyrinth Disorders: Local sensitivity; ototoxicity; vestibular disorder; hearing loss.
Skin and Subcutaneous Tissue Disorders: Burning sensation, stinging, itching (pruritus); dermatitis.
Renal and Urinary Disorders: Gentamicin may cause nephrotoxicity when given systemically. However, it is likely that systemic absorption followingtopical 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 the national reporting system.

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4.9 Overdose

Symptoms: The oral ingestion of the contents of one bottle is unlikely to cause any significant adverse effect.

Management: 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 cause by gentamicin.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: Antiinfectives; **ATC Code:** S03AA06.

Mechanism of Action

Gentamicin exerts a number of effects on cells of susceptible bacteria. It affects the integrity of the plasma membraneand the metabolism of RNA, but it's most important effect is inhibition of protein synthesis at the level of the 30s ribosomal subunit.

Pharmacodynamic Effects

Gentamicin is a bactericidal agent with greater antibacterial activity than streptomycin, neomycin or kanamycin. Gentamicin sulfate is active *in vitro* against many strains of the following microorganisms: *Staphylococcus aureus, Staphylococcus epidermidis, Streptococcus pyogenes, Streptococcus pneumoniae, Enterobacter aerogenes, Escherichia coli, Haemophilus influenzae, Klebsiella pneumoniae, Neisseria gonorrhoeae, Pseudomonas aeruginos*a, and *Serratia marcescens*.

5.2 Pharmacokinetic properties

Topical application of Gentamicin can result in some systemic absorption. Treatment of large areas can result in plasmaconcentrations of up to 1µg/ml.

Gentamicin is not readily absorbed from the gastro-intestinal tract <10% is bound to plasma protein. Gentamicin is excreted >90% in the urine by glomerular filtration. The half-life for its elimination in normal patientsis 2 to 3 hours, but can be increased in cases of renal insufficiency.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety, pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential and toxicity to reproduction.

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

24 months.

6.4 Special precautions for storage

Store the vial well closed at a temperature between 15^0C – 25^0C in a dark place.

6.5 Nature and contents of container <and special equipment for use, administration or implantation>

5ml solution filled in 5ml labeled LDPE vial with spike HIPS cap. One such a bottle is packed in a carton with pack insert.

6.6 Special precautions for disposal <and other handling>

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

7. MARKETING AUTHORISATION HOLDER

Registered Office:

Name: FDC Limited

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8. MARKETING AUTHORISATION NUMBER(S)

Certificate No; 08564/07851/VAR/2022

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Apr 5, 2023

10. DATE OF REVISION OF THE TEXT

September 2023