SUMMARY OF PRODUCT CHARACTERISTICS FOR PHARMACEUTICAL PRODUCTS

1. **Name of the medicinal product :**

   GENTAGLAX EYE/EAR DROPS (Gentamicin Eye/Ear drops BP)

2. **Qualitative and Quantitative composition:**

   Gentamycin Sulphate bp 0.3% W/V

   EDTA

   Methyl Paraben sodium

   Propyl paraben sodium

   Propylene Glycol
   Sodium chloride
   Sodium Dihydrogen phosphate

   Di Sodium Hydrogen BP 5.6 mg Orthophosphates

3. **Pharmaceutical Form**:

   Eye/ ear drops.

4. **Clinical Particulars:**

4.1 Therapeutic indications

Gentaglax eye/ear drops are indicated in adults and children:
1. For the treatment of superficial eye and ear infections caused by organisms sensitive to gentamicin.
2. For prophylaxis against infection in trauma of the eye or ear. 4.2 Posology and method of administration

Posology
Adults, the elderly and the paediatric population
Eyes: 1 or 2 drops should be instilled in 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 cleaned and 2 - 3 drops instilled in the affected ear three to four times a day and at night, or more frequently if required.
Method of administration
Auricular and ocular use.

4.2 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1
Myasthenia gravis
Known or suspected perforation of the ear drum.

4.3 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, 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.

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.

4.4 Interaction with other medicinal products and other forms of interaction

Potent diuretics such as ethacrynic acid and furosemide 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 aminoglycosides to patients who have received curare-type muscle relaxants during anaesthesia.

4.5 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.

Breast-feeding
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
No data available.

4.6 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.

4.7 Undesirable effects

The following adverse reactions are classified by system organ class and ranked under heading of frequency using the following convention:
Not known (cannot be estimated from the available data)

System organ class	Frequency	Undesirable effects
Eye disorders	Not known	- local sensitivity: - vision blurred - eye irritation - burning sensation - stinging sensation - itching (eye pruritus)
Ear and labyrinth disorders	Not known	- local sensitivity - ototoxicity - vestibular disorder: - hearing loss
Skin and subcutaneous tissue disorders	Not known	- burning sensation - stinging - itching (pruritus): - dermatitis.
Renal and disorders	Not known	- nephropathy toxic* - acute renal failure

*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, sensitisation 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 Pharmacy and Poisons Board, Pharmacovigilance Electronic Reporting Systems (PVERS) https://pv.pharmacyboardkenya.org

4.8 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 is mixture of antibiotic substances produced by the growth of micromonosporapurpurea. It is a bactericidal antibiotic which acts by inhibiting protein synthesis. It has 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

Absorption
Topical application of gentamicin can result in some systemic absorption. Treatment of large areas can result in plasma concentrations of up to 1µg/ml.
Distribution
Gentamicin is 70-85% bound to plasma albumin following administration.
Effective plasma concentration is 4 - 8ug/ml
The volume of distribution (VD) is 0.3 1/kg
Elimination
> 90% Gentamicin is excreted unchanged in the urine by glomerular filtration.
T1⁄2 = 2 - 3 hours in individuals with normal kidney function, but can be increased in cases of renal insufficiency.
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

Not relevant.

6. Pharmaceutical particulars

6.1 List of excipients

Benzalkonium chloride BP,
Borax Ph. Eur.,
Sodium chloride Ph. Eur.,
Water for Injection Ph. Eur.

6.2 Incompatibilities

None known**.**

6.3 Shelf life

3 years.
Discard contents 4 weeks after opening.

6.4 Special precautions for storage

Store below 25°C. Do not freeze.

6.5 Nature and contents of container

Gentamicin eye/ear drops are available in 10ml dropper bottles.

6.6 Special precautions for disposal and other handling

No special requirements.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. Marketing authorisation holder

N/A

8. Marketing authorisation number(s)

N/A

9. Date of first authorisation/renewal of the authorisation

N/A

10. Date of revision of the text

11/05/2025