SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

GENTASOL® 0.3% eye drops, solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

5 ml contains: gentamicin 15 mg (as sulphate)

Excipient with known effect:benzalkonium chloride solution
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Eye drops, solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

GENTASOL eye drops are indicated in adults and children:
- For the treatment of superficial eye infections caused by organisms sensitive to gentamicin.
- For prophylaxis against infection in trauma of the eye.

4.2 Posology and method of administration

Adults, the elderly and the paediatric population
1 or 2 drops should be instilled in the affected eye up to 6 times, 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 inredient or to any of the excipients listed in section 6.1.
Myasthenia gravis.

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.

Contact lenses should be removed during the period of treatment of ocular infections.

GENTASOL eye drops contain benzalkonium chloride
May cause eye irritation. Avoid contact with soft lenses. Remove contact lenses prior to application and wait at least 15 minutes before reinsertion. Known to discolour soft contact lenses.

4.5 Interaction with other medicinal products and other forms of interaction

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 or lactation when considered essential by the physician, after careful assessment of the potential risks and benefits.

Breast-feeding
Safety for use 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.

4.7 Effects on ability to drive and use machines

Patients should be advised that the use of Gentasol eye drops in the eye may cause transient blurring of vision. If affected, the patients should not drive or use machines until vision his has cleared.

4.8 Undesirable effects

Eye disorders	Local sensitivity Blurred vision Eye irritation Burning sensation Stinging sensation Itching (eye pruritus)
Skin and subcutaneous disorders	Irritation Burning sensation Stinging Itching (pruritus) Dermatitis
Renal and urinary disorders	Nephrotoxicity* Acute renal failure

* Gentamicin may cause nephrotoxicity when given systematically. 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.

Very rare, cases of dizziness, tinnitus, hypersensitivity and allergic reaction have been reported.

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

4.9 Overdose

No case of overdose has been reported. An excessive use may lead to an increase in the occurrence of undesirable effects.
Gentamine can be removed from blood circulation by hemodialysis or peritoneal dialysis. About 80 % to 90 % of gentamicine can be removed from blood circulation during 12 hours of hemodialysis. Peritoneal dialysis seems to be less effective.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: antibiotic, ATC code: S01AA11
Gentamicin is an aminoglycoside antibiotic.

Mechanism of action
Gentamicin is mixture of antibiotic substances produced by the growth of micromonospora purpurea. 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 1 μg/ml.

Elimination
> 90% Gentamicin is excreted unchanged in the urine by glomerular filtration.

T½ = 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 patients with anuria care must be exercised.

5.3 Preclinical safety data

Not relevant.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium chloride solution, sodium chloride, disodium hydrogen phosphate, sodium dihydrogen phosphate, sodium hydroxide, water for injections.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store at room temperature (below 30 °C). Protect from light. Do not use after 30 days after the bottle opening.

6.5 Nature and contents of container

5 ml bottle of transparent low density polyethylene.
Plastic cap of white low density polyethylene.

6.6 Special precautions for disposal and other handling

No particular requirements.

Bottle opening:

1. With the spike: tighten the cap on the nozzle.
2. The spike in the cap will pierce the tip of the bottle.
3. Dispense drops with gentle pressure. Replace the cap after every use.

7. CATEGORY OF DISTRIBUTION

☐ Other the counter medicines ☒ Prescription only medicines

List I

8. MARKETING AUTHORISATION HOLDER

Exphar sa
Zoning de Nivelles sud, zone 2
Avenue Thomas Edison 105

1402 Thines, Belgium

9. MANUFACTURER

Ahlcon Parenterals (India) Ltd
SP 918, Phase III Bhiwadi
301019 Rajasthan, India

10. UPDATE DATE

January 2019