1. NAME OF THE MEDICINAL PRODUCT

ASCOT Gentamicin Eye/Ear Drops 0.3% W/V

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition:

Gentamicin Sulfate BP Equivalent to Gentamicin Base…. 0.3 % W/V
Benzalkonium Chloride Solution BP…. 0.02 % V/V
Sterile Isotonic Aqueous Base… QS

3. PHARMACEUTICAL FORM

Clear, colourless solution
EYE / EAR drops

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Gentamicin eye/ear drops are indicated:

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

Adults, including the elderly and children

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 For Eye/Ear drops.

4.3 Contraindications

Hypersensitivity to gentamicin or to any of the ingredients. Known or suspected perforation of the ear drum is a contra-indication to use in otitis externa only

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.

4.5 Interaction with other medicinal products and other forms of interaction

Concurrent use with other potentially nephrotoxic or ototoxic drugs should be avoided unless considered essential by the physician

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4.6 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

Irritation, burning, stinging, itching and dermatitis may occur. In the event of irritation, sensitisation or super-infection, treatment should be discontinued and appropriate therapy instituted.
Gentamicin may cause nephrotoxicity when given systemically. However, it is likely that systemic absorption following topical administration does not constitute a comparable risk

4.9 Overdose

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

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antibiotics, ATC code: J01GB03

Mechanism of action:
Gentamicin is a bactericidal antibiotic which acts by inhibiting protein synthesis.

5.2 Pharmacokinetic properties

Topical application of gentamicin can result in some systemic absorption. Treatment of large areas can result in plasma concentrations of up to 1µg/ml.
> 90% Gentamicin is excreted in the urine by glomerular filtration.
< 10% is bound to plasma protein.
T½ = 2 - 3 hours in individuals with normal kidney function, but can be increased in cases of renal insufficiency.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to those already included in other sections of the Summary of Product Characteristics.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Excipient	Specification
Benzalkonium Chloride Solution	BP
Sodium Chloride	BP
Borax	BP
Di-sodium EDTA	BP
Sodium Sulphite	BP
Sodium Hydroxide	BP
Water for Injections	BP
Sodium Chloride	BP

6.2 Incompatibilities:

Nil.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store at a temperature below 30℃. Protect from light..

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

10ml clear colourless solution filled in Sterile plastic bottle with plastic cap (ETO) packed in carton along with insert.

6.6 Special precautions for disposal <and other handling>

No special requirements.

7. MARKETING AUTHORIZATION HOLDER AND MANUFACTURING SITE ADDRESSES

Ascot Pharmacy Ltd
Accra, Ghana.

Manufacturer:
Pharmax India Pvt. Ltd.
9, Kurla Industrial Estate, Ghatkopar (W), Mumbai - 400 086, India.

8. MARKETING AUTHORISATION NUMBER

9. DATE OF FIRST AUTHORIATION OR RENEWAL

10. DATE OF REVISION OF THE TEXT: May 2025

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Where, BP- British Pharmacopoeia

These quantities are calculated on the basis of standard potency and LOD. Quantity may changes if standard potency and LOD changes.

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FDA/SD.245-091713

9. DATE OF FIRST AUTHORIATION OR RENEWAL

12/09/2025

10. DATE OF REVISION OF THE TEXT:

May 2025