

MODULE-1	ADMINISTRATIVE INFORMATION AND PRODUCT INFORMATION
NAME OF THE PRODUCT	GXACIN (Gentamicin Sulfate Ophthalmic Solution USP)

1.6 Product Information

1.6.1 Prescribing Information (Summary of Product Characteristics)

1. Name of the finished Pharmaceutical Product:

GXACIN (Gentamicin Sulfate Ophthalmic Solution USP)

1.1 Strength

0.3%w/v

1.2 Pharmaceutical form

Ophthalmic Solution

2. Qualitative and Quantitative Composition:

2.1 Qualitative declaration

Product Name: GXACIN

Generic Name: Gentamicin Sulfate Ophthalmic Solution USP

Label Claim: Each ml contains:

Gentamicin Sulfate USP

E. q. to Gentamicin.....0.3%w/v

Benzalkonium Chloride Solution BP...0.02%v/v

(As preservative)

Sterile aqueous vehicle.....q.s

2.2 Quantitative declaration

S. No.	Name of Ingredient	Reference	Qty./10ml	Function of Ingredient
1.	*Gentamicin Sulfate USP e.q to Gentamicin	USP	31.490mg	Active Ingredient
2.	Sodium Chloride	USP	46.000mg	Isotonic Agent
3.	Disodium hydrogen orthophosphate	USP	5.490mg	pH adjustment
4.	Sodium dihydrogen orthophosphate	USP	3.054mg	Buffering agent
5.	**Benzalkonium Chloride Solution	BP	0.002ml	Preservative
6.	#Sodium Hydroxide	USP	2.854mg	pH adjustment
7.	Water for Injections	USP	q.s per 10 mL	Vehicle

*Standard Quantity taken with 5% Overages, & are to be dispensed on 100% assay Value.

** This materials is included 5% overages.

This material is used for pH adjustment only, if required

*Std. qty. of Gentamicin Sulfate USP eq. to Gentamicin :- 0.3X10X550X105/100X1000 = 1.732 Kg

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2.3 Salts and hydrates
Sulfate salt of Gentamycin

3. Pharmaceutical Form
Ophthalmic Solution

4. Clinical Particulars

4.1 Therapeutic indications

Treatment of infections of the external structures of the eye and its adnexa caused by susceptible bacteria. Such infections include conjunctivitis, keratitis, keratoconjunctivitis, corneal ulcers, blepharitis and blepharoconjunctivitis, 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.
Also indicated for the treatment of otitis externa.

4.2 Posology and method of administration
Posology

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 more frequently if required.

4.3 Contraindications

Hypersensitivity to active substance, Gentamicin or to any of the excipient.
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 contra-indicated in myasthenia gravis and related conditions.
Perforated tympanic membrane

4.4 Special warnings and precautions for use

Avoid prolonged use. 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 ototoxicity (vestibular damage; 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

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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.

This formulation of Gentamicin Eye/Ear Drops contains benzalkonium chloride as a preservative which may be deposited in soft contact lenses. Hence, Gentamicin should not be used while wearing these 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 otic use of gentamicin, caution is advised when used concomitantly with systemic aminoglycosides.

4.5 Interaction with other medicinal product 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 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 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".

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Eye Disorders:-

Local sensitivity; blurred vision, eye irritation, burning sensation, stinging sensation, itching (eye pruritus)

Ear & Labyrinth Disorders:-

Local sensitivity; ototoxicity; vestibular disorder; hearing loss

Skin & Subcutaneous tissue Disorders:-

burning sensation, stinging, itching (pruritus); dermatitis.

Renal & Urinary Disorders:-

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, sensitivity or super-infection, treatment should be discontinued and appropriate therapy instituted.

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

Pharmacotherapeutic group: Ophthalmologicals; Antibiotics

ATC Code: S01AA11

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 its most important effect is inhibition of protein synthesis at the level of the 30s ribosomal subunit.

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.

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

Effective plasma concentration is 4 - 8ug/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 the SPC.

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6.0 Pharmaceutical particulars

6.1 List of Excipients

Sodium chloride USP, Disodium hydrogen orthophosphate USP, Sodium dihydrogen orthophosphate USP, Benzalkonium chloride solution BP, Sodium hydroxide USP, Water for injection USP

6.2 Incompatibilities

None known.

6.3 Shelf life

24 months from the date of manufacturing.

6.4 Special precautions for storage

Store below 30°C. Protect from light. Do not refrigerate or freeze.

6.5 Nature and contents of container

10 ml LDPE vial packed in a unit carton along with pack insert

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Tighten the cap on the nozzle as shown.

The spike in the cap will pierce the tip of the vial.

Dispense drops with gentle pressure.

Replace the cap after every use.

Not for Injection. For External Use Only

Use the solution within one month after opening the vial.

7. Marketing Authorization Holder

Axa Parenterals Limited

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Vill. Kishanpur, Jamalpur, Roorkee-247667

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E-Mail: axapar@axapar.com

8. Marketing Authorization Number(s)

NA

9. Date of first authorization/renewal of the authorization

NA

10. Date of revision of the text

NA