NEW ZEALAND DATA SHEET

GENOPTIC® Eye Drops

1.PRODUCT NAME

GENOPTIC® 0.3% w/w eye drops

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Gentamicin sulfate equivalent to 3 mg gentamicin (0.3% w/w)

For a full list of excipients, see section 6.1 List of excipients

3. PHARMACEUTICAL FORM

Gentamicin sulfate is a white to buff hygroscopic powder which is freely soluble in water, ethylene glycol and formamide. It is practically insoluble in alcohol, acetone, chloroform and ether. Gentamicin sulfate is a mixture of the sulfates of gentamicin C1, gentamicin C1A and gentamicin C2. When dry, gentamicin sulfate contains not less than 590 units of gentamicin per mg. GENOPTIC® eye drops are a sterile, aqueous solution buffered to approximately pH 7.0 for use in the eye.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

GENOPTIC® eye drops are indicated in the topical treatment of infections of the external eye and its adnexa caused by susceptible bacteria. Such infections include conjunctivitis, keratitis, keratoconjunctivitis, corneal ulcers, blepharitis, blepharoconjunctivitis, acute meibomianitis and dacryocystitis.

4.2 Dosage and Administration

Instil one or two drops of GENOPTIC® eye drops into the affected eye(s) every four hours. In severe infections, dosage may be increased to a maximum of 2 drops once every hour.

In order to minimise systemic absorption of GENOPTIC® eye drops, apply pressure to the tear duct immediately following administration of the drug.

Paediatric population:
Safety and effectiveness of GENOPTIC® eye drops in paediatric patients have not been established

Elderly population:
Safety and effectiveness of GENOPTIC® eye drops in elderly patients have not been established.

4.3 Contraindications

Hypersensitivity to gentamicin sulfate or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

GENOPTIC® eye drops are not for injection. It should never be injected subconjunctivally, nor should it be introduced directly into the anterior chamber of the eye.

Prolonged use of topical antibiotics may give rise to overgrowth of nonsusceptible organisms, such as fungi. Bacterial resistance to gentamicin may also develop. Should this occur, or if irritation or hypersensitivity to any component of the product develops, or purulent discharge, inflammation or pain becomes aggravated, discontinue use of the preparation and institute appropriate therapy.

Patients should be advised not to wear contact lenses if they have signs and symptoms of bacterial ocular infection. Patients wearing soft (hydrophilic) contact lenses should be instructed to remove contact lenses before administration of the drug and wait 10-15 minutes after instilling GENOPTIC® eye drops before reinserting soft contact lenses. Patients should be advised that the preservative in GENOPTIC® eye drops, benzalkonium chloride, may be absorbed by soft contact lenses.

To prevent eye injury or contaminating the dropper tip and solution, patients should be advised not to touch the eyelids, the surrounding area or any surface with the dropper tip of the bottle .

4.5 Interaction with other medicines and other forms of interaction

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

Pregnancy: Category D.

Gentamicin and other aminoglycosides cross the placenta. There is evidence of selective uptake of gentamicin by the foetal kidney resulting in damage (probably reversible) to immature nephrons. Eighth cranial nerve damage has also been reported following in-utero exposure to some of the aminoglycosides. Because of their chemical similarity, all aminoglycosides must be considered potentially nephrotoxic and ototoxic to the foetus. It should also be noted that therapeutic blood levels in the mother do not equate with safety for the foetus.

There are no adequate and well-controlled studies of GENOPTIC® eye drops in pregnant women. Gentamicin should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus.

Breastfeeding: Studies on the use of GENOPTIC® eye drops during lactation have not been conducted.

Because many drugs are excreted in human milk, caution should be exercised when GENOPTIC® eye drops is administered to a nursing woman.

4.7 Effects on ability to drive and use machines

Upon instillation of GENOPTIC®, patients may experience transient blurred vision which may impair the ability to drive or use machinery. If affected, patients should not drive or use machinery until their vision has cleared.

4.8 Undesirable effects

Transient irritation has been reported with the use of GENOPTIC® eye drops.

Post-Marketing experience:
The following adverse reactions have been identified during post-marketing use of GENOPTIC® eye drops:

- Conjunctival hyperaemia
- Ocular hyperaemia
- Eye discharge
- Eye irritation
- Eye pain
- Eye oedema
- Hypersensitivity including eyelid irritation, eyelid oedema, eye swelling.

4.9 Overdose

In case of overdosage, immediately flush the eye(s) with water or normal saline.

If ingested accidently, patients should be advised to drink plenty of liquid to dilute and seek medical direction.

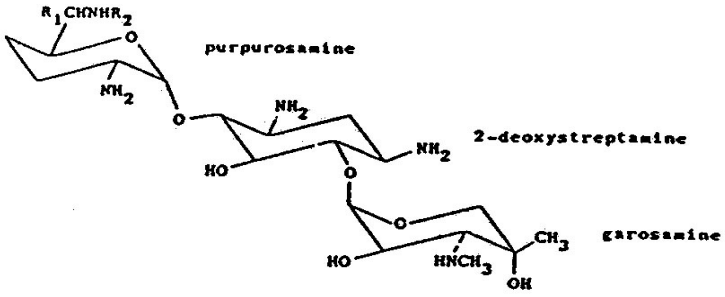
For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5. PHARMACOLOGICAL PROPERTIES

Chemical Name:
O-3-deoxy-4-C-methyl-3-(methylamino)-β-L-arabinopyranosyl-(1→6)-O-[2,6-diamino-2,3,4,6-tetradeoxy-α-D-erythro-hexopyranosyl-(1→4)]-2-deoxy-D-streptamine.

Empirical formula:
Gentamicin C_1: $C_{21}H_{43}N_5O_7$
Gentamicin C_{1A}: $C_{19}H_{39}N_5O_7$
Gentamicin C_2: $C_{20}H_{41}N_5O_7$

Structural Formula:
Gentamicin



Gentamicin C_1: $R_1 = R_2 = CH_3$
Gentamicin C_{1A}: $R_1 = R_2 = H$
Gentamicin C_2: $R_1 = CH_3$ $R_2 = H$

5.1 Pharmacodynamic properties

Pharmacotherapeutic group:
Opthalmologicals, Antiinfectives, Antibiotics
ATC code: S01AA11

Mechanism of action:
Gentamicin sulfate is a water soluble antibiotic of the aminoglycoside group which has shown activity against a wide variety of pathogenic gram-negative and gram-positive bacteria. The gram-positive bacteria against which gentamicin sulfate is active include coagulase positive and negative staphylococci.

The gram-negative bacteria against which gentamicin sulfate is active include certain strains of *Pseudomonas aeruginosa*, indole positive and indole negative Proteus species, *Escherichia coli, Klebsiella pneumoniae*, (Friedlander's bacillus), *Haemophilus influenzae and Haemophilus aegyptius* (Koch-Weeks bacillus), *Aerobacter aerogenes, Moraxella lacunata* (diplobacillus of Morax-Axenfeld), and Neisseria species, including *Neisseria gonorrhoeae.*

At this time there are increasing members of resistant cases being reported for the aminoglycoside class of antibiotics, particularly to Streptococcus pneumoniae. This phenomenon will also reduce the synergy with the β-lactam class of drugs as combination therapy. This should be considered when commencing therapy for all ocular infections and the results of therapy should be closely monitored for signs of inefficiency. Should this occur, more aggressive pharmacotherapeutic options, e.g. a cephalosporin, should be used.

5.2 Pharmacokinetic properties

Studies on the pharmacokinetics of ophthalmic preparations of gentamicin sulfate have not been conducted.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Preservative:
benzalkonium chloride

Inactives:

Polyvinyl alcohol (LIQUIFILM®), disodium edetate, sodium phosphate dibasic, sodium chloride and purified water.

6.2 Incompatabilities

Not applicable.

6.3 Shelf Life

2 years

6.4 Special precautions for storage

Store below 25°C.

Discard unused contents 4 weeks after opening the bottle.

Contents are sterile if seal is intact.

To avoid contamination of the solution, keep container tightly closed.

Do not touch dropper tip to any surface

6.5 Nature and content of container

5 mL (dropper bottle)

6.6 Special precautions for disposal

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

7. MEDICINE SCHEDULE

Prescription Only Medicine

8. SPONSOR

Name and Address

Allergan New Zealand Limited,
Corner of Manu Tapu Drive and
Joseph Hammond Place
Auckland International Airport
Mangere
AUCKLAND
Toll free telephone: 0800 659 912

9.DATE OF FIRST APPROVAL

December 1984

10. DATE OF REVISION OF THE TEXT :

April 2019

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SUMMARY TABLE OF CHANGES

Sections changed	Summary of new information
4.7	Included information regarding the effects on ability to drive and use machines.
6.6	Included information on special precautions for disposal.
All headings amended to align to Medsafe's updated DS requirements and sections within the Data Sheet have been moved under the appropriate headings in line with Medsafe's updated DS requirements.	
Minor editorial changes, including typographical and grammatical amendments, implemented throughout the DS to ensure legibility of this document.	