PROFESSIONAL INFORMATION LEAFLET

SCHEDULING STATUS **S4**

1. NAME OF THE MEDICINE

Toryn® 3 mg/ml Ophthalmic Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Excipient with known effect:

Preservative: Benzalkonium Chloride 0,01 % *m/v*

For full list of excipients, see section 6.1.

3. PHARMACEUTIAL FORM

Ophthalmic solution.

Transparent, colourless solution free from visible particles.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

TORYN is a topical antibiotic indicated in the treatment of external bacterial infections of the eye and its adnexa, caused by susceptible organisms. Appropriate monitoring of bacterial response to topical antibiotic therapy should accompany the use of TORYN.

4.2 Posology and method of administration

Posology:

Instil 1 or 2 drops into the affected eye(s) every 4 hours.

In severe infections, instil 2 drops into the eye(s) every hour until improvement, following which treatment should be reduced prior to discontinuation.

4.3 Contraindications

TORYN is contraindicated in patients with hypersensitivity to aminoglycosides, tobramycin or any other ingredient in TORYN.

4.4 Special warnings and precautions for use

- Prolonged use of TORYN may result in overgrowth of non-susceptible organisms, including fungi, or lead to skin sensitisation. Appropriate therapy should be initiated if superinfection occurs.
- If topical ocular tobramycin such as TORYN is administered together with systemic aminoglycoside antibiotics, care should be taken to monitor the total serum concentration (see section 4.5).
- As the possibility of adverse effects on the corneal permeability, and the danger of disruption of the corneal epithelium with prolonged or repeated usage of benzalkonium chloride preserved ophthalmological preparations, cannot be excluded, regular ophthalmological examination is required.
- Caution should be exercised in the use of benzalkonium chloride preserved topical medicine over an extended period in patients with extensive ocular surface disease.
- Avoid contact with soft contact lenses.
- Some patients may experience sensitivity to topically applied aminoglycosides. Discontinue use should a sensitivity reaction to TORYN occur.
- The use of TORYN with topical corticosteroids may mask clinical signs of bacterial, fungal or viral infections (see section 4.5).

4.5 Interaction with other medicines and other forms of interaction

Take special care when TORYN is given to patients receiving other medicines which are ototoxic, nephrotoxic, neurotoxic or have neuromuscular blocking activity.
Patients must be instructed to remove contact lenses prior to application of TORYN and wait for 15 minutes after installation of the dose before reinsertion.
TORYN and carbenicillin have been reported to have an enhanced effect, however *in vitro* incompatibility with carbenicillin sodium has been demonstrated. Therefore, if both these antibiotics are required, it is recommended that they be administered separately.
If TORYN is administered together with systemic aminoglycoside antibiotics, care should be taken to monitor the total serum concentration (see section 4.4).
The use of TORYN with topical corticosteroids may mask clinical signs of bacterial, fungal or viral infections (see section 4.4).

4.6 Fertility, pregnancy and lactation

Since there are no adequate and well controlled studies of tobramycin such as TORYN in pregnant women, its safety and/or efficacy has not been established.

There is a potential for adverse reactions in nursing infants and therefore a decision should be made whether to discontinue nursing the infant or discontinue the use of TORYN, taking into account the importance of the medicine to the mother.

4.7 Effects on ability to drive and use machines:

Administration of eye drops may temporarily cause blurred vision or other visual disturbances which may affect the ability to drive or use machines. If blurred vision occurs, the patient must wait until the vision is clear before driving or using machines.

4.8 Undesirable effects

Infections and infestations:	
Less frequent:	Eye infection (exacerbation or secondary).
Immune system disorders:	
Less frequent :	Hypersensitivity (local).
Eye disorders:	
Less frequent:	Eye irritation (burning and stinging upon instillation), ocular hyperaemia, blurred vision, eyelid oedema, eyelid pruritis, eye pain (periorbital).
Frequency unknown:	Localised ocular toxicity.
Skin and subcutaneous tissue disorders:	
Less frequent:	Erythema (periorbital).

4.9 Overdose

Discontinue use immediately.

A topical overdose of TORYN may be flushed from the eye(s) with lukewarm tap water.

5. PHARMACOLOGICAL PROPERTIES

Pharmacological classification: A.15.1 Ophthalmic preparations with antibiotics and/or sulphonamides.

Tobramycin is a basic water-soluble aminoglycoside antibiotic and has a spectrum of activity similar to that of gentamycin.

5.1 Pharmacodynamic properties

Tobramycin is bactericidal in action and acts by inhibiting protein synthesis in susceptible bacteria by irreversibly binding to 30S ribosomal subunits.

There is evidence of transmissible resistance.

Cross resistance to other aminoglycosides may occur.

Inherently resistant species:

Aerobic Gram-positive micro-organisms:

Enterococcus species, *Staphylococcus aureus* methicillin-resistant,

Staphylococcus epidermidis methicillin-resistant, *Streptococcus*

pneumoniae, Streptococcus species.

Aerobic Gram-negative micro-organisms:

Burkholderia cepacia, Stenotrophomonas maltophilia.

Anaerobic micro-organisms:

Strict anaerobic bacteria.

Others:

Chlamydia species, *Mycoplasma* species, *Rickettsia* species.

5.2 Pharmacokinetic properties

Tobramycin is poorly absorbed across the cornea and conjunctiva and absorption of tobramycin into the aqueous humour is enhanced in the presence of corneal abrasion.

Tobramycin is excreted primarily in urine.

Minimal amounts are absorbed into the eye after topical administration of tobramycin.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Disodium edetate dihydrate

Purified water

Sodium chloride

Sodium sulphate anhydrous

Tyloxapol.

Preservative: 0,01 % *m/v* benzalkonium chloride.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

Unopened: 2 years

Do not use more than 30 days after opening.

6.4 Special precautions for storage

Store at or below 30 ºC. Protect from light.

Keep the bottle in the carton until required for use.

Keep well closed after initial opening.

Do not refrigerate or freeze.

KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of container

TORYN Ophthalmic Solution is supplied in an opaque white sterile dropper bottle with a white sterile capillary plug and a white sterile cap, containing 5 ml solution.

The dropper bottle is contained in an outer cardboard carton.

6.6 Special precautions for disposal and other handling

No special requirements.

An unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. HOLDER OF THE CERTIFICATE OF REGISTRATION

Gen-Eye (Pty) Ltd[1]
Royal Palm Business Estate
Unit 7, 646 Washington Street
Halfway House, Midrand, 1685
Gauteng, South Africa

8. REGISTRATION NUMBER

46/15.1/0942

9. DATE OF FIRST AUTHORISATION

12 May 2020

10. DATE OF REVISION OF THE TEXT

17 September 2021

® - TORYN is a registered trademark of Gen-Eye (Pty) Ltd.

[1] Company Registration number: 2009/009360/07

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