NEW ZEALAND DATA SHEET

1 SOFRAMYCIN 5 MG/ML EAR/EYE DROPS

Soframycin 5 mg/mL Ear/Eye Drops

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Framycetin sulfate 5 mg/mL (0.55% w/v)

Excipient with known effect: Benzalkonium chloride.

For the full list of excipients, see Section 6.1 List of excipients.

3 PHARMACEUTICAL FORM

Ear/Eye Drops

Soframycin is a clear bright colourless aqueous solution.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

In the eye: Conjunctivitis, blepharitis, styes, corneal abrasions and burns. Prophylactically following removal of foreign bodies. Also indicated for corneal ulcers.

In the ear: Otitis externa.

4.2 DOSE AND METHOD OF ADMINISTRATION

Dose

In the eye: 2 drops every one or two hours initially, diminishing to 2 or 3 drops three times daily.

In the ear: 2 or 3 drops may be instilled into the external auditory meatus thrice daily; or a wick may be saturated with drops.

Elderly

No dosage adjustment is necessary.

Paediatric population

No dosage adjustment is necessary.

Method of administration

For ophthalmic and otic administration.

4.3 CONTRAINDICATIONS

Known hypersensitivity to framycetin sulfate or to any of the excipients listed in Section 6.1.

Soframycin is contraindicated in case of eardrum perforation.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

In patients known to be allergic to other aminoglycoside antibiotics (neomycin, paromomycin, kanamycin), cross-sensitisation to framycetin sulfate may occur, but not invariably so.

Aminoglycoside antibiotics may cause irreversible, partial or total deafness when applied topically to open wounds or damaged skin. This effect is aggrevated by renal or hepatic impairment and by prolonged duration of treatment. The treatment should not be continued after resolution of symptoms.

There have been reported cases of ototoxicity with aminoglycosides administered to patients with mitochondrial mutations, particularly the m.1555A>G mutation, which suggests an increased risk of ototoxicity in these patients, including cases where the patient's aminoglycoside serum levels were within the recommended range. Some cases were associated with a maternal history of deafness and/or mitochondrial mutation. Mitochondrial mutations are rare, and the penetrance of this observed effect is unknown.

Although no cases were identified with topical preparations of neomycin, framycetin or gentamicin, the potential for a similar effect with framycetin and other aminoglycosides administered topically cannot be ruled out.

Contact with soft contact lenses should be avoided. Contact lenses should be removed prior to application and patients should wait at least 15 minutes before reinsertion. The excipient Benzalkonium chloride is known to discolour soft contact lenses.

Use in the elderly

No data available.

Paediatric use

No data available.

Effects on laboratory tests

No data available.

4.5 INTERACTION WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTION

No data available.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

No data available.

Pregnancy

Category D

Gentamicin and other aminoglycosides cross the placenta. There is evidence of selective uptake of gentamicin by the foetal kidney resulting in cellular 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 available data on Soframycin use in pregnant women. No conclusions can be drawn regarding whether or not Soframycin is safe for use during pregnancy. Soframycin should be used during pregnancy only if the potential benefits to the mother outweigh the potential risks, including those to the foetus.

Breast-Feeding

There are no available data on the presence of Soframycin in human milk, milk production, or the effects on the breastfed infant. No conclusions can be drawn regarding whether or not Soframycin is safe for use during breastfeeding. Soframycin should be used during breastfeeding only if the potential benefits to the mother outweigh the potential risks, including those to the breastfed child.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Use in the eye will cause blurring of the vision on application. Patients should be warned not to drive or operate hazardous machinery unless vision is clear.

4.8 UNDESIRABLE EFFECTS

Hypersensitivity reactions may occur after topical use of aminoglycoside antibiotics (see Section 4.4). Benzalkonium chloride which is used as a preservative in the ear/eye drops can cause irritation to eyes and induce hypersensitivity reactions.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions at https://nzphvc.otago.ac.nz/reporting/.

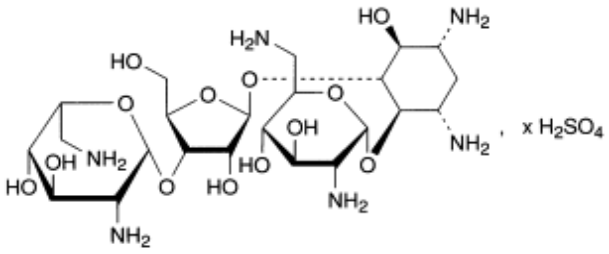
4.9 OVERDOSE

Oral ingestion of the contents of one bottle (up to 8 mL) is unlikely to lead to any serious adverse effects.

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

5 PHARMACOLOGICAL PROPERTIES

Chemical structure



$C_{23}H_{46}N_6O_{13},xH_2SO_4$ 615 (base)

CAS number

The CAS number is 4146-30-9

5.1 PHARMACODYNAMIC PROPERTIES

Pharmacotherapeutic group: Antibiotics, ATC code: S01AA07

Framycetin sulfate is an aminoglycoside bactericidal antibiotic. It is active against a wide variety of both Gram-positive and Gram-negative bacteria commonly found in superficial eye infections: staphylococci (including strains resistant to other antibiotics), *Pseudomonas aeruginosa*, coliform bacteria and pneumococci. It is exceptionally well tolerated by the tissues of the eye. Preparations containing it are non-irritant.

Clinical trials

No data available.

5.2 PHARMACOKINETIC PROPERTIES

Absorption

No data available.

Distribution

No data available.

Metabolism

No data available.

Excretion

No data available.

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

No data available.

Carcinogenicity

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

benzalkonium chloride (as a preservative),

citric acid monohydrate,

sodium chloride,

sodium citrate dihydrate

purified water.

6.2 INCOMPATIBILITIES

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

6.3 SHELF LIFE

3 years

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 25ºC.

6.5 NATURE AND CONTENTS OF CONTAINER

Ear/Eye Drops: 8 mL bottle.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

No special requirements.

7 MEDICINE SCHEDULE

Prescription Medicine

8 SPONSOR

Pharmacy Retailing (NZ) Ltd t/a Healthcare Logistics
PO Box 62027
Sylvia Park Auckland 1644
Freecall: 0800 283 684

Email: medinfo.australia@sanofi.com

9 DATE OF FIRST APPROVAL

31 December 1969

10 DATE OF REVISION OF THE TEXT

16 August 2022

Table 1 - Summary of Changes

Section	Change
8	Change to Sponsor