AUSTRALIAN PRODUCT INFORMATION – SOFRAMYCIN (FRAMYCETIN)

1 NAME OF THE MEDICINE

Framycetin sulfate

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

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

3 PHARMACEUTICAL FORM

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

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

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 Streptomyces-derived 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 aggravated 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 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

No data available.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

No data available.

Use in 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.

Use in lactation

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

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of this registration.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

Local allergic reactions of the hypersensitivity type have rarely been reported.

Reporting Suspected Adverse Effects

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at www.tga.gov.au/reporting-problems (Australia) or https://nzphvc.otago.ac.nz/reporting/ (New Zealand).

4.9 OVERDOSE

For information on the management of overdose, contact the Poisons Information Centre, telephone number 13 11 26 (Australia) or the National Poisons Centre, 0800 POISON or 0800 764 766 (New Zealand).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Pharmacotherapeutic group: Antibiotics, ATC code: S01AA07

Mechanism of action

Framycetin sulfate is a 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, coliforms 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

citric acid monohydrate
sodium citrate dihydrate
sodium chloride
water for injections
benzalkonium chloride (as a preservative).

6.2 INCOMPATIBILITIES

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

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 25°C

6.5 NATURES AND CONTENTS OF CONTAINER

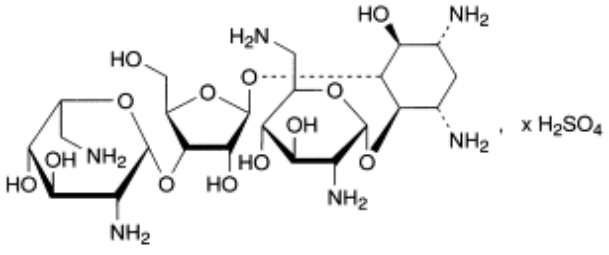
Eye/Ear Drops: 8mL bottle.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

In Australia, any unused medicine or waste material should be disposed of by taking to your local pharmacy.

6.7 PHYSICOCHEMICAL PROPERTIES

Chemical structure



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

CAS number

4146-30-9

7 MEDICINE SCHEDULE (POISONS STANDARD)

S4

8 SPONSOR

sanofi-aventis australia pty ltd
12-24 Talavera Road
Macquarie Park NSW 2113

Tel: 1800 818 806

Email: medinfo.australia@sanofi.com

9 DATE OF FIRST APPROVAL

07 January 1994

10 DATE OF REVISION

10 June 2022

10.1 SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information
4.4	New warning of Aminoglycosides and aminoglycosides combinations produced toxicity in individuals with mitochondrial mutations.
6.1	Changed excipient names to align with ARTG record.
1	Changed the text to only include AAN of active
2	Remove the text “Excipients with known effect: Benzalkonium chloride” in line with TGO 91

4.8	Insert the mandatory subheading “Reporting suspected adverse effects”
6.7	Remove text “The CAS Number is”
8	Addition of contact details