DATA SHEET

1 SOFRAMYCIN 5 MG/ML EAR/EAR 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 (see section 4.8).

For the full list of excipients, see section 6.1.

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 because of the risk of ototoxicity.

### 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

In patients known to be allergic to other aminoglycoside antibiotics (neomycin, 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.

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.

### 4.5 INTERACTION WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTION

Not relevant to topical use.

### 4.6 FERTILITY, PREGNANCY AND LACTATION

**Pregnancy**

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.

**Breast-Feeding**

No data available.

**Fertility**

No data available.

### 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 [https://nzphvc.otago.ac.nz/reporting/](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

#### 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.

**5.2 PHARMACOKINETIC PROPERTIES**

Not relevant to topical use.

**5.3 PRECLINICAL SAFETY DATA**

No data available.

**6 PHARMACEUTICAL PARTICULARS**

**6.1 LIST OF EXCIPIENTS**

- benzalkonium chloride,
- citric acid monohydrate,
- sodium chloride,
- sodium citrate dihydrate
- purified water.

**6.2 INCOMPATIBILITIES**

Not applicable.

**6.3 SHELF LIFE**

3 years

**6.4 SPECIAL PRECAUTIONS FOR STORAGE**

Store below 25°C.

**6.5 NATURE AND CONTENTS OF CONTAINER**

Ear/Eye Drops 1 x 8 mL glass bottle with rubber dropper top.
**6.6 SPECIAL PRECAUTIONS FOR DISPOSAL**

No special requirements.

**7 MEDICINE SCHEDULE**

Prescription Medicine

**8 SPONSOR**

sanofi-aventis new zealand limited  
Level 8,  
56 Cawley Street  
Ellerslie, Auckland  
Free Call: 0800 283 684

**9 DATE OF FIRST APPROVAL**

31 December 1969

**10 DATE OF REVISION OF THE TEXT**

25 January 2018

<table>
<thead>
<tr>
<th>Section</th>
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<tbody>
<tr>
<td>All</td>
<td>Align with Medsafe data sheet format including minor text additions to meet requirements.</td>
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<tr>
<td>3</td>
<td>Update to product description</td>
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<tr>
<td>4.3</td>
<td>Additional contraindications</td>
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| 4.4 | Revised precaution on amionglucoside antibiotics.  
Addition of precaution regarding excipient Benzalkonium chloride. |
| 5.1 | Addition of ATC code |
| 6.5 | Addition of packaging material |