

# AUSTRALIAN PRODUCT INFORMATION – SOFRAMYCIN (FRAMYCETIN)

## 1 NAME OF THE MEDICINE

Soframycin (framycetin sulfate) 5 mg/mL ear/eye drops

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Excipients with known effect: Benzalkonium chloride.

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.

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 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](http://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 – anhydrous  
sodium citrate  
sodium chloride  
water-purified  
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

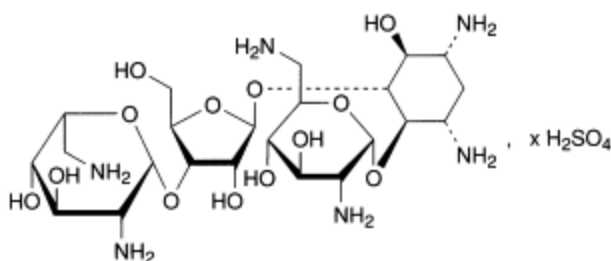
Eye/Ear Drops: 8mL bottle.

### 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



$\text{C}_{23}\text{H}_{46}\text{N}_6\text{O}_{13} \cdot x \text{H}_2\text{SO}_4$  615 (base)

#### CAS number

The CAS number is 4146-30-9

## 7 MEDICINE SCHEDULE (POISONS STANDARD)

S4

## 8 SPONSOR

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

## 9 DATE OF FIRST APPROVAL

07 January 1994

## 10 DATE OF REVISION

02 October 2019

### 10.1 SUMMARY TABLE OF CHANGES

<b>Section Changed</b>	<b>Summary of new information</b>
4.6	Revision to text regarding use in pregnancy and lactation