

Data Sheet

SOFRAMYCIN Ear/Eye Drops

Name of Medicine

Framycetin sulfate 5mg/ml

Presentation

Soframycin Ear/Eye Drops are sterile, clear, colourless drops.

Uses

Actions

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.

Pharmacokinetics

Not relevant to topical use.

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.

Dosage and 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.

Elderly

No dosage adjustment is necessary.

Children

No dosage adjustment is necessary.

Contraindications

Known hypersensitivity to framycetin sulfate; perforation of the tympanic membrane.

Warnings and Precautions

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 given systemically or when applied topically to open wounds or damaged skin. This effect is dose related and is enhanced by renal or hepatic impairment. Although this effect has not been

reported following topical treatment the possibility should be considered when high dose topical treatment is given to small children or infants.

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.

Effect 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.

Adverse Effects

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

Interactions

Not relevant to topical use.

Overdosage

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

Pharmaceutical Precautions

Special Precautions for Storage

Store below 25°C.

Medicine Classification

Prescription Medicine

Package Quantities

Ear/Eye Drops 1 x 8 ml bottle

Further Information

Soframycin Ear/Eye Drops also contain benzalkonium chloride, citric acid monohydrate, sodium chloride, sodium citrate dihydrate and purified water.

Name and Address

sanofi-aventis new zealand limited
Level 8, James and Wells Tower
56 Cawley Street
Ellerslie, Auckland

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