

Data Sheet

SOFRADEX Ear/Eye Drops

Name of Medicine

Each mL of drops contains framycetin sulfate 5mg, gramicidin 0.05mg and dexamethasone 0.5mg.

Presentation

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

Uses

Actions

Framycetin sulfate is an aminoglycoside bactericidal antibiotic active against a wide variety of 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.

Gramicidin reinforces the action of framycetin sulfate against streptococci.

Dexamethasone is a highly potent topical corticosteroid. Its topical superiority is particularly apparent in cases in which other corticosteroids have failed.

Pharmacokinetics

Not relevant to topical use.

Indications

In the eye: For the short term treatment of steroid responsive conditions of the eye when prophylactic antibiotic treatment is also required, after excluding the presence of fungal or viral disease.

In the ear: Otitis externa.

Dosage and Administration

Adults

In the eye: 1 or 2 drops applied to each affected eye up to six times daily or more frequently if required.

In the ear: 2 or 3 drops instilled into the ear three or four times daily.

Elderly

No dosage adjustment is necessary.

Children

No dosage adjustment is necessary.

Contraindications

Viral, fungal, tuberculous or purulent conditions of the eye. Use is contraindicated if glaucoma is present or herpetic keratitis (eg dendritic ulcer) is considered a possibility. Use of topical steroids in the latter condition can lead to extension of the ulcer and marked visual deterioration.

Otitis externa should not be treated when the eardrum is perforated because of the risk of ototoxicity.

Hypersensitivity to Sofradex.

Warnings and Precautions

Topical corticosteroids should never be given for an undiagnosed red eye as inappropriate use is potentially blinding.

Treatment with corticosteroid/antibiotic combinations should not be continued for more than seven days in the absence of clinical improvement since prolonged use may lead to occult extension of infection due to the masking effect of the steroid. Prolonged use may lead to skin sensitisation and the emergence of resistant organisms.

Prolonged use may lead to the risk of adrenal suppression in infants.

Treatment with corticosteroid preparations should not be repeated or prolonged without regular review to exclude raised intraocular pressure, cataract formation or unsuspected infections.

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 ocular use, the possibility should be considered when high dose topical treatment is given to small children or infants.

Pregnancy and Lactation

Safety for use in pregnancy and lactation has not been established. There is inadequate evidence of safety in human pregnancy.

Topical administration of corticosteroids in pregnant animals can cause abnormalities of foetal development including cleft palate and intrauterine growth retardation. There may therefore be a very small risk of such effects in the human foetus.

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 vision on application. Patients should be warned not to drive or operate hazardous machinery unless vision is clear.

Adverse Effects

Hypersensitivity reactions, usually of the delayed type may occur leading to irritation, burning, stinging, itching and dermatitis.

Topical steroid use may result in increased intraocular pressure leading to optic nerve damage, reduced visual acuity and visual field defects.

Intensive or prolonged use of topical corticosteroids may lead to formation of posterior subcapsular cataracts. In those diseases causing thinning of the cornea or sclera, corticosteroid therapy may result in thinning of the globe leading to perforation.

Interactions

Not relevant to topical use.

Overdosage

Long term intensive topical use may lead to systemic effects.

Oral ingestion of the contents of the 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

Sofradex Ear/Eye Drops: Bottles of 8ml

Further Information

Sofradex Ear/Eye Drops also contain phenethyl alcohol, methylated spirit - industrial, citric acid monohydrate, sodium citrate, lithium chloride, polysorbate 80 and water - purified.

Name and Address

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

Date of Preparation

19 February 2009