

# NEW ZEALAND DATA SHEET

## 1 PRODUCT NAME

SOFRADEX, Ear/Eye Drops

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

For full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Ear/Eye Drops

Sterile, clear, colourless drops

## 4 CLINICAL PARTICULARS

### 4.1 THERAPEUTIC 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.

### 4.2 DOSE AND METHOD OF ADMINISTRATION

#### Dosage

#### *Adults, Elderly and Children*

**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.

(No dosage adjustment is necessary for the Elderly and Children).

## **Administration**

Auricular and Ocular use.

### **4.3 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.

### **4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE**

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 applied topically to open wounds or damaged skin. This effect is aggravated by renal or hepatic impairment and prolonged by duration of treatment. The treatment should not be continued after resolution of symptoms.

Visual disturbance may be associated with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) (Section 4.8).

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

Not relevant to topical use.

#### **4.6 FERTILITY, 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.

#### **4.7 EFFECTS 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.

#### **4.8 UNDESIRABLE 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.

Eye disorders:

Not known: blurred vision, chorioretinopathy.

#### **4.9 OVERDOSE**

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.

## **5 PHARMACOLOGICAL PROPERTIES**

### **5.1 PHARMACODYNAMIC PROPERTIES**

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.

### **5.2 PHARMACOKINETIC PROPERTIES**

Not relevant to topical use.

### **5.3 PRECLINICAL SAFETY DATA**

Not applicable

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 LIST OF EXCIPIENTS**

Phenethyl alcohol

Methylated spirit - industrial

Citric acid monohydrate

Sodium citrate

Lithium chloride

Polysorbate 80

Sodium hydroxide (for pH-adjustment)

Hydrochloric acid (for pH-adjustment)

Water - purified.

### **6.2 INCOMPATIBILITIES**

Not applicable

### **6.3 SHELF LIFE**

24 months from date of manufacture

Discard 4 weeks after opening

### **6.4 SPECIAL PRECAUTIONS FOR STORAGE**

Store below 25°C.

### **6.5 NATURE AND CONTENTS OF CONTAINER**

Glass bottle fitted with dropper attachment – Pack size 8ml

### **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

## **9 DATE OF FIRST APPROVAL**

31 December 1969

## **10 DATE OF REVISION OF THE TEXT**

01 February 2018

### **SUMMARY TABLE OF CHANGES**

<b>SECTION</b>	<b>ADDITIONAL TEXT ADDED</b>
4.4	Revised precaution regarding aminoglycoside antibiotics; additional precaution regarding visual disturbance.
4.8	Additional adverse events