

# PRODUCT INFORMATION

## SOFRADEX® EAR DROPS

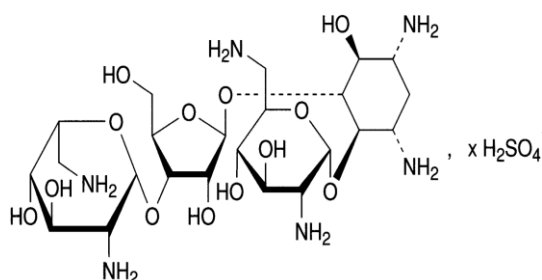
### NAME OF THE MEDICINE

#### Non-proprietary Name

Each mL contains framycetin sulfate 5mg, gramicidin 50µg and dexamethasone (as sodium metasulfobenzoate) 500µg.

#### Chemical Structure

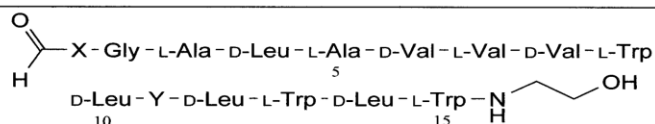
Framycetin sulfate



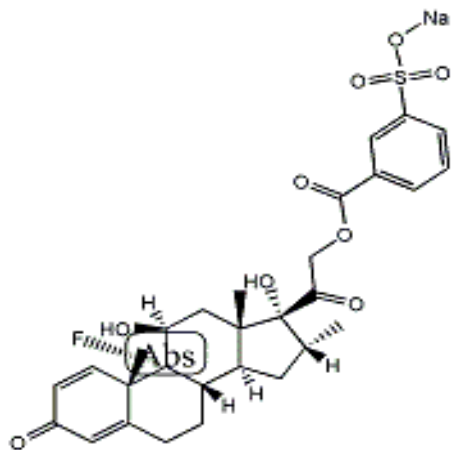
*Molecular weight – 712.72*

#### Gramicidin

| Gramicidin | X     | Y     | Mol. formula   | $M_r$ |
|------------|-------|-------|--|-------|
| A1         | L-Val | L-Trp | $\text{C}_{99}\text{H}_{140}\text{N}_{20}\text{O}_{17}$  | 1882  |
| A2         | L-Ile | L-Trp | $\text{C}_{100}\text{H}_{142}\text{N}_{20}\text{O}_{17}$ | 1896  |
| B1         | L-Val | L-Phe | $\text{C}_{97}\text{H}_{139}\text{N}_{19}\text{O}_{17}$  | 1843  |
| C1         | L-Val | L-Tyr | $\text{C}_{97}\text{H}_{139}\text{N}_{19}\text{O}_{18}$  | 1859  |
| C2         | L-Ile | L-Tyr | $\text{C}_{98}\text{H}_{141}\text{N}_{19}\text{O}_{18}$  | 1873  |



#### Dexamethasone sodium metasulfobenzoate



*Molecular Weight – 598.6*

## **CAS number**

Framycetin sulphate – 4146-30-9

Gramicidin – 1405-97-6

Dexamethasone sodium metasulfobenzoate – 3936-02-5

## **DESCRIPTION**

Sofradex is a clear bright colourless aqueous solution. It also contains polysorbate 80, industrial methylated spirit, citric acid monohydrate, sodium citrate, lithium chloride, purified water and is preserved with phenethyl alcohol.

## **PHARMACOLOGY**

Framycetin sulfate is a bactericidal antibiotic active against a wide variety of Gram-positive and Gram-negative bacteria commonly found in superficial infections; staphylococci (including strains resistant to other antibiotics), *Pseudomonas aeruginosa*, coliforms 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.

## **INDICATIONS**

Inflammatory and allergic conditions of the ear, e.g. otitis externa. Eczema of the auditory meatus is often present and causes inflammation, exudation and pruritus, which are all rapidly relieved by dexamethasone. Infection, often secondary to scratching, is generally due to staphylococci, *E. coli*, *Pseudomonas* and *Proteus spp.* which respond rapidly to framycetin sulfate.

## **CONTRAINDICATIONS**

Known hypersensitivity to framycetin sulfate; viral and tubercular lesions; varicella, vaccinia; perforation of tympanic membrane.

## **PRECAUTIONS**

In patients known to be allergic to Streptomyces-derived antibiotics (neomycin, paromomycin, kanamycin), cross-sensitisation to framycetin sulfate may occur, but not invariably so.

### **Use in Pregnancy – (Category D)**

Gentamicin and other aminoglycosides cross the placenta. There is evidence of selective uptake of aminoglycosides by the fetal kidney resulting in 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 concentrations in the mother do not equate with safety for the foetus.

## **ADVERSE EFFECTS**

Local allergic reactions of the hypersensitivity type have rarely been reported.

## **DOSAGE AND ADMINISTRATION**

2 or 3 drops should be instilled into the ear three or four times daily; alternatively, a gauze wick kept saturated with the drops may be inserted into the external auditory meatus.

**PRESENTATION AND STORAGE CONDITIONS**

8mL bottles

Store below 25°C. Do not refrigerate.

Discard 4 weeks after opening.

**NAME AND ADDRESS OF THE SPONSOR**

sanofi-aventis australia Pty Ltd

12-24 Talavera Road

Macquarie Park NSW 2113

**POISON SCHEDULE OF THE MEDICINE**

S4

Date of most recent amendment: 14 January 2010