PRODUCT INFORMATION
SOFRADEX EAR DROPS

NAME OF THE MEDICINE

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

DESCRIPTION
Sofradex is a clear bright colourless aqueous solution. It contains polysorbate 80, methylated spirit - industrial, citric acid monohydrate, sodium citrate, lithium chloride, water – purified 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 REACTIONS
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
8mL bottles

NAME AND ADDRESS OF THE SPONSOR
sanofi-aventis australia ptty ltd
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Macquarie Park NSW 2113

POISON SCHEDULE OF THE MEDICINE
S4

Date of most recent amendment: 11 November 2009