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 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.

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.

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
12 January 2017

SUMMARY TABLE OF CHANGES

<table>
<thead>
<tr>
<th>SECTION</th>
<th>ADDITIONAL TEXT ADDED</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 QUALITATIVE AND QUANTITATIVE COMPOSITION</td>
<td>For full list of excipients, see section 6.1.</td>
</tr>
<tr>
<td>4.2 Dose and method of administration</td>
<td>Auricular and Ocular use.</td>
</tr>
<tr>
<td>5.3 Preclinical safety data</td>
<td>Not applicable</td>
</tr>
<tr>
<td>6.1 List of excipients</td>
<td>(for pH-adjustment) added after Sodium hydroxide and Hydrochloric acid</td>
</tr>
<tr>
<td>6.2 Incompatibilities</td>
<td>Not applicable</td>
</tr>
<tr>
<td>6.3 Shelf life</td>
<td>Discard 4 weeks after opening</td>
</tr>
<tr>
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</tbody>
</table>

Format changed in accordance with the updated data sheet SPC-style format
Below highlights all differences between the current and the new formatted Datasheet document