Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Sofradex Ear/Eye Drops

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Contains Framycetin Sulphate 0.5 %w/v (5mg/ml), Gramicidin 0.005% w/v (0.05 mg/ml), Dexamethasone sodium metasulphobenzoate equivalent to Dexamethasone 0.05% w/v (0.5 mg/ml).

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Ear/Eye drops, solution.

Practically clear, colourless to slightly green-yellow aqueous solution.

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 and viral disease.

In the ear
Otitis externa.

4.2 Posology and method of administration

Route of administration: Auricular and Ocular.

Adults (and the elderly) and children

In the eye
One or two drops applied to each affected eye up to six times daily or more frequently if required.

In the ear
Two or three drops instilled into the ear three or four times daily.

Treatment duration should be short (not exceed 7 days) (see section 4.4).

4.3 Contraindications

Use in patients hypersensitive to the active ingredients.

Use in the presence of infections of viral, treponemal, tuberculous or of non-sensitive fungal origin.

Use in infants.

The product should not be used if there is a perforation of the tympanic membrane (eardrum perforation), as entry into the middle ear could lead to ototoxicity.

Use is contraindicated if glaucoma is present or herpetic keratitis (e.g. 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.

4.4 Special warnings and precautions for use

Prolonged use of an anti-infective may result in the development of superinfection due to organisms, including fungi, resistant to anti-infective.

Treatment with corticosteroid/antibiotic combinations should not be continued for more than 7 days in the absence of any clinical improvement, since prolonged use may lead to occult extension of infections due to the masking effect of the steroid. Prolonged use may also lead to skin sensitisation and the emergence of resistant organisims.

Prolonged use in the eye may lead to corneal thinning with perforation or cataract locally. Prolonged topical use may lead to raised intra-ocular pressure. Treatment with corticosteroid preparations should not be repeated or prolonged without regular review to exclude raised intra-ocular pressure, cataract formation or unsuspected infections.

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

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

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. This effect is aggravated by renal or hepatic impairment and by prolonged duration of treatment. The treatment should not be continued after resolution of symptoms. 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.

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

Cushing's syndrome and/or adrenal suppression associated with systemic absorption of ocular dexamethasone may occur after intensive or long-term continuous therapy in predisposed patients, including children and patients treated with CYP3A4 inhibitors (including ritonavir and cobicistat). In these cases, treatment should be progressively discontinued.

Visual disturbance
Visual disturbance may be reported 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) which have been reported after use of systemic and topical corticosteroids.

4.5 Interaction with other medicinal products and other forms of interactions

CYP3A4 inhibitors (including ritonavir and cobicistat-containing products) may decrease dexamethasone clearance resulting in increased effects and adrenal suppression/Cushing’s syndrome. The combination should be avoided unless the benefit outweighs the increased risk of systemic corticosteroid side-effects, in which case patients should be monitored for systemic corticosteroid effects.

4.6 Fertility, pregnancy and lactation

Prolonged use or extensive use should be avoided during pregnancy or lactation in human beings since safety for use in pregnancy and lactation has not been established. There is inadequate evidence of safety in human pregnancy. Topical administration of corticosteroids to 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. There is a risk of foetal ototoxicity if aminoglycoside antibiotic preparations are administered during pregnancy.

4.7 Effects on ability to drive and use machines

May cause transient blurring of vision on instillation. Warn patients 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 intro-ocular pressure leading to optic nerve damage, reduced visual acuity and visual field defects.

Eye disorders:
Uncommon: blurred vision, chorioretinopathy (see also section 4.4)

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 the thinning of the globe leading to perforation.

Endocrine disorders
Cushing's syndrome, adrenal suppression (see section 4.4) (frequency not known)

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

Long-term intensive topical use may lead to systemic effects.

Oral ingestion of the contents of one bottle (up to 10 ml) is unlikely to lead to any serious adverse effects.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Framycetin sulphate is an aminoglycoside antibiotic with a spectrum of activity similar to that of neomycin, this includes *Staph. Aureus* and most clinically significant gram negative organisms.

Gramicidin is an antimicrobial cyclic polypeptide active *in vitro* against gram positive bacteria. It is used for the local treatment and susceptible infections, sometimes in combination with other antimicrobial agents and frequently with a corticosteroid.

Dexamethasone is a synthetic glucocorticoid and has the general properties as other corticosteroids.

5.2 Pharmacokinetic properties

Framycetin sulphate absorption occurs from inflamed skin and wounds. Once absorbed it is rapidly excreted by the kidneys in active form. It has been reported to have a half-life of 2-3 hours.

Gramicidin has properties similar to those of tyrothricin and is too toxic to be administered systemically.

Dexamethasone is readily absorbed from the gastro-intestinal tract. It has a biological half-life in plasma of about 190 minutes.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Anhydrous Citric Acid
Sodium Citrate
Lithium Chloride
Phenylethyl Alcohol
Industrial Methylated Spirits
Polysorbate 80
Water for Injection
Sodium Hydroxide
Dilute Hydrochloric Acid

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Unopened: 2 years.

Opened: Discard contents 28 days after first opening.

6.4 Special precautions for storage

Do not store above 25°C.

Do not refrigerate.

6.5 Nature and contents of container

5, 8 or 10ml amber glass vials or polypropylene bottles effectively sealed and fitted with a silicone rubber teat dropper under a protective, blue, plastic cap.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Sanofi-Aventis Ireland Limited T/A SANOFI
Citywest Business Campus
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0540/070/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st April 1977

Date of last renewal: 10th August 2009

10 DATE OF REVISION OF THE TEXT

May 2019