Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Sofradex Ear/Eye Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

The ointment contains Framycetin Sulphate 5mg/g (0.5% w/w), Dexamethasone 0.5mg/g (0.05% w/w) and Gramicidin 0.05mg/g (0.005% w/w).

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Ointment.

A clear to white, translucent, smooth homogenous sterile, greasy ointment.

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.
- Application to the eyelid: Blepharitis.

4.2 Posology and method of adminstration

Route of administration: Topical

Adults (and the elderly) and children:

In the eye: Apply sparingly two or three times daily, or at night if drop treatment is given during the day.

In the ear: Apply once or twice daily.

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, 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 special 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.

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 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.

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

4.5 Interaction with other medicinal products and other forms of interaction

Non-relevant to topical use.

4.6 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

Will cause blurring on application. 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.

4.9 Overdose

Long-term intensive topical use may lead to systemic 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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Plastibase 30 W
(dispersed polyethylene in mineral oil)

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

Unopened: 3 years
Opened: Discard contents 28 days after first opening.

6.4 Special precautions for storage

Do not refrigerate.
Do not store above 25°C.

6.5 Nature and contents of container

5g white pigment plasticised PVC tube with tamper evident seal or white multilaminated tube (aluminium foil barrier/inner coating HDPE) with tamper evident seal.

6.6 Instructions for use and handling

No special requirements.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

PA 6/10/2

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 10th August 2004

10 DATE OF REVISION OF THE TEXT

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