Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Soframycin Eye Drops 5mg/ml

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Framycetin Sulphate 0.5 % w/v (5mg/ml)

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Eye Drops, solution

A clear, bright, sterile, aqueous solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the topical treatment of superficial bacterial infections of the eye due to micro-organisms sensitive to the anti-infective.

Soframycin is used for the treatment of bacterial infections of the eye, notably conjunctivitis and blepharitis, for styes, corneal abrasions and burns, and prophylactically following the removal of foreign bodies. It is also indicated for corneal ulcers (alone or as a complement to the use of Soframycin by sub-conjunctival injection).

4.2 Posology and method of adminstration

Topical, into conjunctival sac.

Application one to three times daily.

For rapid effect, preferably during the daytime, one or two drops every one or two hours should be instilled in acute conditions (generally for two or three days), reducing to 1 or 2 drops three or four times daily

4.3 Contraindications

Known hypersensitivity to framycetin or chemically related antibiotics or any of the other components in the preparation

4.4 Special warnings and special precautions for use

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

Aminoglycosides have been reported to cause irreversible partial or total deafness when given systemically, topically to open wounds or broken skin and intraperitoneally. These effects have not been reported with topical ocular administration of framycetin. However, the possibility should be considered when using high dose topical treatment in

the elderly, small children or those patients with renal or hepatic impairment.

In cases of severe infections, the topical use of framycetin should be supplemented with appropriate systemic treatment.

Contact lenses should be removed during period of treatment

4.5 Interaction with other medicinal products and other forms of interaction

None relevant to topical use.

4.6 Pregnancy and lactation

There is inadequate evidence for the safety of framycetin in pregnancy and lactation. However, it has been used for many years with no direct evidence of ill consequences. Use should be only when considered essential by the physician.

4.7 Effects on ability to drive and use machines

Topical eye preparations may cause transient blurring of vision on instillation. 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 with local treatment with framycetin (cross-sensitivity with other aminoglycoside antibiotics may occur). Irritation, stinging or burning, itching and dermatitis may sometimes occur.

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Framycetin is an aminoglycoside antibiotic with a broad spectrum of antibiotic activity. Framycetin sulphate is poorly absorbed after topical administration.

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. The reported half-life of framycetin sulphate is 2-3 hours.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Anhydrous citric acid
Sodium citrate
Sodium chloride
Benzalkonium chloride solution
Purified water
Sodium hydroxide
Hydrochloric acid

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 store above 25°C.
Keep container in the outer carton.

6.5 Nature and contents of container

Flexible polypropylene dropper bottle fitted with a plug and cap.

6.6 Instructions for use and handling

No special requirements.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

PA 6/11/1

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Date of last renewal: 10th August 2004

10 DATE OF REVISION OF THE TEXT

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