

## Part II

### Summary of Product Characteristics

#### 1 NAME OF THE MEDICINAL PRODUCT

Soframycin Eye Ointment 5mg/g

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Framycetin Sulphate 0.5% w/w (5mg/g)

For excipients, see 6.1.

#### 3 PHARMACEUTICAL FORM

Eye Ointment

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

#### 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 administration

Topical, into conjunctival sac.

For continued effect, three applications of the ointment daily or at bedtime if drops have been used during the day.

##### 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**

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 store above 25°C.

## **6.5 Nature and contents of container**

Aluminium/polyethylene multilaminate collapsible tubes containing 5g of ointment.

## **6.6 Instructions for use and handling**

No special requirements.

## **7 MARKETING AUTHORISATION HOLDER**

Roussel Laboratories Ltd.,  
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Uxbridge,  
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## **8 MARKETING AUTHORISATION NUMBER**

PA 6/11/2

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 1<sup>st</sup> April 1992

Date of last renewal: 10<sup>th</sup> August 2004

## **10 DATE OF REVISION OF THE TEXT**

September 2004