Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Minims Neomycin Sulphate 0.5% w/v

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

0.5% w/v solution of Neomycin sulphate.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Sterile single-use eye drops solution

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the topical treatment of superficial ocular infections caused by sensitive pathogens.

4.2 Posology and method of administration

1 to 2 drops every 1 to 4 hours or as directed by the physician.

4.3 Contraindications

Hypersensitivity to neomycin or to any other component of the preparation. (Cross-sensitivity with other aminoglycoside antibiotics may occur).

4.4 Special warnings and precautions for use

a) In severe infections topical use of neomycin should be supplemented with appropriate systemic treatment.

b) Prolonged use should be avoided as it may lead to superinfection by resistant organisms, including fungi.

c) Prolonged or extended use to denuded epidermis may result in absorption leading to toxicity.

d) Neomycin 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.

e) Contact lenses should be removed during the period of treatment.

f) Systemic absorption may be reduced by compressing the lacrimal sac at the medial canthus for a minute during and following the instillation of the drops. (This blocks the passage of the drops via the nasolacrimal duct to the wide absorptive area of the nasal and pharyngeal mucosa. It is especially advisable in children.

4.5 Interaction with other medicinal products and other forms of interaction

None relevant to topical use.

4.6 Pregnancy and lactation

Safety for use in pregnancy and lactation has not been established therefore use only when considered essential by the physician.

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 until vision is clear.

4.8 Undesirable effects

Hypersensitivity reactions, usually of the delayed type, occur frequently with local treatment with neomycin. Irritation, burning, stinging, itching and dermatitis may occur.

4.9 Overdose

Please see 4.4 d).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Neomycin is a broad spectrum antibiotic effective against a wide range of Gram-positive and Gram-negative micro-organisms. It has no activity against viruses or fungi.

5.2 Pharmacokinetic properties

No specific human topical ocular pharmacokinetic data are available.

5.3 Preclinical safety data

No unexpected safety issues were identified during the development of this product.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium dihydrogen phosphate
Disodium edetate
Purified water

6.2 Incompatibilities

None applicable.

6.3 Shelf Life

15 months.

6.4 Special precautions for storage

Do not store above 25°C. Do not freeze. Protect from light.

6.5 Nature and contents of container

A sealed conical shaped polypropylene container fitted with a twist and pull off cap. Each Minims unit is overwrapped in an individual polypropylene/paper pouch.

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

Each Minims unit should be discarded after a single use.

7 MARKETING AUTHORISATION HOLDER

Chauvin Pharmaceuticals Limited
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8 MARKETING AUTHORISATION NUMBER

PA 118/3/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 April 1977

Date of last renewal: 01 April 2002

10 DATE OF REVISION OF THE TEXT

April 2002