IRISH MEDICINES BOARD ACT 1995

MEDICINAL PRODUCTS(LICENSING AND SALE)REGULATIONS, 1998

(S.I. No.142 of 1998)

PA0118/032/001
Case No: 2025987

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Chauvin Pharmaceuticals Limited

106 London Road, **Kingston-upon-Thames**, **KT2 6TN**, **United Kingdom**

an authorisation, subject to the provisions of the said Regulations, in respect of the product

MINIMS GENTAMICIM SULPHATE

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **28/11/2006** until **04/01/2009**.

Signed on behalf of the Irish Medicines Board this

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A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Minims Gentamicin Sulphate

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Gentamicin Sulphate equivalent to 0.3% w/v gentamicin base.

For excipients, see 6.1

3 PHARMACEUTICAL FORM

Eye drops, solution.

Single-use, clear, colourless, sterile eye drops, solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the topical treatment of ocular infections due to organisms sensitive to gentamicin.

4.2 Posology and method of administration

Adults (including the elderly):

One drop up to four times daily.

4.3 Contraindications

Gentamicin should not be used in patients with a known hypersensitivity to gentamicin or other aminoglycosides.

4.4 Special warnings and precautions for use

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

Repeated application to damaged or denuded surfaces may allow significant systemic absorption with resultant toxicity.

4.5 Interaction with other medicinal products and other forms of interaction

Concurrent use with other eye preparations should be avoided unless considered essential by the physician.

4.6 Pregnancy and lactation

The use of gentamicin during pregnancy or lactation is not recommended.

4.7 Effects on ability to drive and use machines

May cause blurred vision on instillation. If affected, do not drive until vision is restored.

4.8 Undesirable effects

Transient blurring of vision may occur on instillation.

4.9 Overdose

As Minims are single-dose units, overdose is unlikely to occur.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Gentamicin is an aminoglycoside which has a bactericidal action. It acts by inhibiting protein synthesis in susceptible bacteria.

5.2 Pharmacokinetic properties

Gentamicin pharmacokinetics conform to a two-compartment model, in which the drug is rapidly eliminated from the tissue compartment. Its biological half-life is 1 - 4 hours.

With regard to ocular pharmacokinetics, gentamicin is not very lipid-soluble and thus it does not easily pass through the corneal epithelium. However, gentamicin 0.3% drops do penetrate into the aqueous humour of normal and inflamed eyes at significant therapeutic levels.

Only very low levels of gentamicin will be absorbed systemically. Gentamicin is 25 - 30% protein bound and is excreted in the urine.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Purified Water
Sodium Chloride
Borax
Sodium Hydroxide

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

15 months.

6.4 Special precautions for storage

Store below 25ºC. Do not freeze. Store in the original container.

6.5 Nature and contents of container

A sealed conical shaped polypropylene container fitted with a twist and pull off cap made from Ph.Eur. grade polypropylene for containers and closures for parenteral and ophthalmic preparations. Each Minims unit is overwrapped in an individual polypropylene/paper pouch. Each container holds approximately 0.5ml of solution. Each carton contains 20 units.

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 Ltd.
106 London Road,
Kingston-Upon Thames,
Surrey,
KT2 6TN,
United Kingdom.

8 MARKETING AUTHORISATION NUMBER

PA 118/32/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 5 January 1984

Date of last renewal: 5 January 2004

10 DATE OF REVISION OF THE TEXT

November 2006