Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Isopto Plain 0.5% eye drops, solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Hypromellose 0.5% w/v.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution
A clear and colourless to almost colourless eye drops solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Used topically to provide tear-like lubrication for the symptomatic relief of dry eyes and eye irritation associated with deficient tear production.

Also used as an ocular lubricant for artificial eyes.

4.2 Posology and method of administration

Adults, children and the elderly:

The dose depends on the need for lubrication. Usually one to two drops to each eye three times daily or as prescribed.

4.3 Contraindications

Hypersensitivity to any component of the product. The product contains benzalkonium chloride and should not be used when soft contact lenses are worn.

4.4 Special warnings and precautions for use

If irritation persists or worsens, or headache, eye pain, vision changes or continued redness occur, discontinue use and consult a physician.

To preserve sterility do not allow the dropper to touch the eye or any other surface.

4.5 Interaction with other medicinal products and other forms of interaction

Hypromellose may prolong the contact time of topically applied drugs commonly used in ophthalmology.

4.6 Pregnancy and lactation

There is insufficient evidence as to safety in pregnancy and this product should, therefore, only be used in pregnancy if it is considered essential by the physician.

4.7 Effects on ability to drive and use machines

May cause transient blurring of vision on instillation. Do not drive or operate hazardous machinery unless vision is clear.

4.8 Undesirable effects

May cause transient mild stinging or temporarily blurred vision.

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Hypromellose is an inert substance. It has no pharmacological activity.

5.2 Pharmacokinetic properties

Hypromellose is an inert substance. It has no pharmacological activity and, hence, the pharmacokinetic properties have not been studied.

5.3 Preclinical safety data

Hypromellose is an inert substance and is not expected to be absorbed systemically. Hence, although no systemic toxicity studies have been conducted it is not expected to demonstrate any systemic toxicity or to have any effect on reproductive processes.

Similarly no specific local ocular toxicity or irritation studies have been conducted, however, no adverse effects are anticipated. Indeed, hypromellose ophthalmic solution is used as a control in some ophthalmic drug studies because of the acknowledged low level of toxicity.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium citrate dihydrate
Anhydrous disodium hydrogen phosphate
Sodium dihydrogen phosphate monohydrate
Sodium chloride
Benzalkonium chloride
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years (unopened), 1 month (after first opening).

6.4 Special precautions for storage

Do not store above 25°C.
Do not refrigerate.
Keep container tightly closed.

6.5 Nature and contents of container

10 ml Drop-Tainer- Natural Low Density Polyethylene Bottle and Plug. Polystyrene or Polypropylene cap.

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

No special requirements.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

PA 290/12/1

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10 DATE OF REVISION OF THE TEXT

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