Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Celluvisc 0.5% w/v, eye drops, solution, unit dose

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains 5mg carmellose sodium

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Eye drops, solution in single-dose container.

Product imported from Spain

Clear, colourless to slightly yellow solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Tear substitute. Treatment of the symptoms of dry eye.

4.2 Posology and method of administration

Instil 1-2 drops in the affected eye/s 4 times a day or as needed.

Ensure that the single-dose container is intact before use. The eye drop solution should be used immediately after opening.

To avoid contamination do not touch the tip to the eye or any other surface.

If Celluvisc is concomitantly used with other ocular eye medications there must be an interval of at least 15 minutes between the two medications (as displacement of a medication may occur).

The eye drops may be used with contact lenses.

4.3 Contraindications

Hypersensitivity to carmellose sodium or to any of the excipients.

4.4 Special warnings and precautions for use

If irritation, pain, redness or changes in vision occur or if the patient’s condition is worsened, treatment discontinuation should be considered and a new assessment made.

4.5 Interaction with other medicinal products and other forms of interaction

None known.
For the use of concomitant ocular products, see section 4.2.

4.6 Fertility, pregnancy and lactation

Due to the negligible systemic exposure and the lack of pharmacological activity Celluvisc can be used during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

Celluvisc is not expected to cause blurred vision. If individual patients experience transient blurred vision they should be advised not to drive or operate machinery until vision has cleared.

4.8 Undesirable effects

The frequency of adverse reactions documented during clinical trials is given. The frequency is defined as follows: Very Common (≥ 1/10); Common (≥ 1/100, <1/10); Uncommon (≥ 1/1,000, <1/100); Rare (≥1/10,000, <1/1,000); Very Rare (<1/10,000), not known (cannot be estimated from the available data).

Eye disorders:
Common: Eye Irritation

The following other adverse reactions have reported since Celluvisc has been marketed:

Eye pain, vision blurred, lacrimation increased, ocular hyperaemia.

4.9 Overdose

Accidental overdose will present no hazard.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other ophthalmologicals
ATC code: S01XA20
Carmellose sodium has no pharmacological effect. Carmellose sodium has a high viscosity resulting in an increased retention time on the eye.
The excipients in Celluvisc were chosen to mimic the electrolyte constitution of tears.

5.2 Pharmacokinetic properties

Due to the high molecular weight (approx 90,000 Daltons) carmellose sodium is unlikely to penetrate the cornea.

5.3 Preclinical safety data

There are no preclinical data considered relevant to clinical safety beyond data included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride
Sodium lactate
Potassium chloride
Calcium chloride
Magnesium chloride

Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on each single-dose container.
and outer package of the product on the market in the country of origin.
After first opening: Use immediately.

6.4 Special precautions for storage

Do not store above 25ºC.

6.5 Nature and contents of container

0.4 ml in LDPE single-dose container.
Pack sizes: 30 single-dose containers.

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

Discard any unused solution in opened container i.e. do not re-use container for subsequent doses.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/28/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 12th November 2010

10 DATE OF REVISION OF THE TEXT

October 2012