Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Celluvisc 1% w/v Eye drops, solution, unit dose

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains 10 mg carmellose sodium.

One drop (» 0.05 ml) contains 0.5 mg of carmellose sodium.
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution
A clear, colourless to slightly yellow viscous solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment of the symptoms of dry eye.

4.2 Posology and method of administration

Instil one or two drops in the affected eye/s as needed.
Ensure that the single-dose container is intact before use. The eye drop solution should be used immediately after opening.

Concomitant ocular medication should be administered 15 minutes apart from the instillation of Celluvisc.

Paediatric population
The safety and efficacy of Celluvisc in Paediatric population have not been established. No data are available.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

If irritation, pain, redness and changes in vision occur or worsen, treatment should be discontinued and a new assessment considered.
Contact lenses should be removed before each application and may be inserted after 15 minutes.
To avoid contamination or possible eye injury, do not touch the tip of the vial to any surface and avoid contact with the eye.
Discard open single dose container after use.

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

Pregnancy and Breast-feeding

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

4.7 Effects on ability to drive and use machines

Celluvisc has minor or moderate influence on the ability to drive and use machines as it may cause transient blurring of vision which may impair the ability to drive or operate machines. Do not drive or use machinery unless vision is clear.

4.8 Undesirable effects

The frequency of adverse reactions documented during clinical trials is defined as follows:

- Very Common (³ 1/10)
- Common (³ 1/100, < 1/10)
- Uncommon (³ 1/1 000, < 1/100)
- Rare (³ 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 (including burning and discomfort), eye pain, eye pruritus, visual disturbance.

Postmarketing Experience

The following additional adverse reactions have been identified during postmarketing use of Celluvisc 1.0% in clinical practice.

Immune System Disorders

Uncommon: Hypersensitivity including eye allergy with symptoms of eye swelling or eyelid edema.

Eye Disorders

Uncommon: Lacrimation increased, vision blurred, eye discharge, eyelid margin crusting and/or medication residue, foreign body sensation in eye, ocular hyperemia, visual impairment.

Injury, Poisoning and Procedural Complications

Uncommon: Superficial injury of eye (*from the vial tip touching the eye during administration)* and/or corneal abrasion

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via: HPRA Pharmacovigilance

Website: www.hpra.ie

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.

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

No additional information of relevance for the doctor has been obtained from the preclinical testing.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride
Sodium lactate
Potassium chloride
Calcium chloride dihydrate
Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.
The eye drop solution should be used immediately after opening. Any unused solution should be discarded.

6.4 Special precautions for storage

Do not store above 25°C.
Keep the single dose containers in the pouch and place the pouch back in the outer carton. Pouch is required to prevent moisture loss.

6.5 Nature and contents of container

Clear, single-dose containers made from low density polyethylene formed with a twist-off tab.
Each unit is filled with 0.4 ml of solution.
Pack sizes:
Carton containing 10, 20, 30, 40, 60 or 90 foil pouched single-dose containers. Each foil pouch contains 10 single-dose containers.
Not all pack sizes may be marketed.

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

Ensure that the single dose container is intact before use. Discard any unused solution (i.e. once opened do not re-use container for subsequent doses).

6.6 Special precautions for disposal

Ensure that the single dose container is intact before use. Discard any unused solution (i.e. once opened do not re-use container for subsequent doses). The product should be discarded after the expiration date.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

AbbVie Limited
Citywest Business Campus
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA1824/016/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23rd April 1997

Date of last renewal: 3rd October 2008

10 DATE OF REVISION OF THE TEXT

April 2025