# 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 the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Eye drops, solution in single-dose container.
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 or possible eye injury, do not touch tip of the bottle or vial to any surface and avoid contact with the eye.

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.

*Paediatric population*
The safety and efficacy of Celluvisc in children and adolescents have been established by clinical experience, but no clinical trial data are available. The posology recommended in adults is recommended in the paediatric population.

### 4.3 Contraindications

Hypersensitivity to carmellose sodium or to any of the excipients listed in section 6.1.

### 4.4 Special warnings and precautions for use

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

### 4.5 Interaction with other medicinal products and other forms of interactions

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 may cause transient blurring of vision which may impair the ability to drive or operate machines. The patient should wait until their vision has cleared before driving or using machinery.

**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 (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 in clinical practice. Because postmarketing reporting of these reactions is voluntary and from a population of uncertain size, it is not always possible to reliably estimate the frequency of these reactions.

***Immune System Disorders:***
Hypersensitivity including eye allergy.

***Eye Disorders:***
Blurred vision, eye discharge, lacrimation increased, ocular hyperemia.

***Injury, Poisons and Procedural Complications:***
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, Earlsfort Terrace, IRL - Dublin 2;
Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@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.
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 dihydrate
Magnesium chloride hexahydrate
Sodium hydroxide or Hydrochloric acid (for pH adjustment)
Purified water

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

18 months.
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: 5, 30 or 90 single-dose containers.
Not all pack sizes may be marketed.

### 6.6 Special precautions for disposal

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

## 7 MARKETING AUTHORISATION HOLDER

AbbVie Limited
Citywest Business Campus
Co Dublin 24
Ireland

## 8 MARKETING AUTHORISATION NUMBER

PA1824/016/002

## 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10 November 2006
Date of last renewal: 30 September 2009

## 10 DATE OF REVISION OF THE TEXT

April 2022