

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Cellufluid, eye drops, solution, single-dose container

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 Cellufluid 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 Cellufluid 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 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

Pregnancy and Breast-feeding

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

4.7 Effects on ability to drive and use machines

Cellufluid 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 ($\geq 1/10$); Common ($\geq 1/100$, $<1/10$); Uncommon ($\geq 1/1,000$, $<1/100$); Rare ($\geq 1/10,000$, $<1/1,000$); 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 Cellufluid 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 the national reporting system listed in Appendix V.

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 Cellufluid 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 to adjust pH

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 25°C.

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 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. MARKETING AUTHORISATION HOLDER

<[To be completed nationally]>

8. MARKETING AUTHORISATION NUMBER

<[To be completed nationally]>

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 4 August 2005.

Date of latest renewal: 30 March 2010

10. DATE OF REVISION OF THE TEXT

15 May 2014