

SUMMARY OF PRODUCT INFORMATION

1. NAME OF THE MEDICAL DEVICE

CELLUSAN 1% w/v, eye drops, solution, reclosable vial and bottle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains 10 mg carmellose sodium

For the full list of excipients, see 5.1.

3. PRODUCT FORM

Eye drops, solution in 0.4mg daily-dose reclosable vial and preservative-free, multidose 10ml bottle. Sterile clear solution.

4. CLINICAL PARTICULARS

4.1 Suggested Use

Tear substitute. CELLUSAN is used to obtain long lasting and soothing relief from moderate to severe dry eyes. It also provides protection against burning, irritation and discomfort associated with ocular dryness or exposure to environmental factors. The product is preservative-free and suitable for use with contact lenses. It may also be placed directly on the contact lenses to make the insertion much more comfortable.

4.2 Posology and method of administration

Unless otherwise directed, instill 1 drop in the eye one or more times daily, according to necessity. For external ocular use only. Suitable for use in adults and children.

To avoid contamination or possible eye injury, do not touch the tip of the bottle or vial to any surface and avoid contact with the eye. Leave an interval of at least 15 minutes before instilling other eye drops.

4.3 Contraindications

Hypersensitivity to carmellose sodium or any of the ingredients listed in section 5.1.

4.4 Special warnings and precautions for use

Stop use and consult a physician if irritation, pain, redness, or changes in vision occur, persist, or worsen or new eye signs or symptoms develop.

4.5 Interaction with 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

There are no known fertility implications with the use of CELLUSAN. No effects during pregnancy and on the breastfed infant are anticipated. Can be used during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

After administration, in rare cases, a slight temporary blurring of vision may be observed due to

the viscosity of the solution; it is therefore advisable to wait for a few seconds before any activity that requires clear vision. If affected wait until vision is completely clear before driving or operating machinery.

4.8 Undesirable effects

Brief blurred vision or a slight stinging sensation on instilling. Hypersensitivity to any of the ingredients.

4.9 Overdose

No case of overdose has been reported.

5. PRODUCT PARTICULARS

GMDN Classification: Code 44237 – lubricant eye drops

CND Classification: Q0299 – Ophthalmic devices - other

Carmellose sodium has no pharmacological effect. Carmellose sodium has a high viscosity resulting in an increased retention time on the eye.

5.1 List of excipients

Lactic acid

Sodium hydroxide

Sodium chloride

Potassium chloride

Calcium chloride dihydrate

Water for injections

5.2 Incompatibilities

Not applicable.

5.3 Shelf life

Reclosable vial: 3 years. Once opened, each vial can be used for up to 12 hours.

Preservative-free, multidose bottle: 3 years. Once opened, the bottle can be used for up to 90 days. Do not use if the container is damaged or after the expiry date shown.

5.4 Special precautions for storage

Store below 25°C

6. MANUFACTURER AND CONTACT DETAILS

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8. DATE OF REVISION OF THE TEXT

April 2023