เอกสารกำกับยาภาษาอังกฤษ

(เหมือนกันทุกขนาดบรรจุ)

Summary of Product Characteristics

MELLUTEAR

Carmellose sodium Eye Drops 0.5% W/V

1. Name of the medicinal product

MELLUTEAR

carmellose sodium 5 mg/mL

2. Qualitative and quantitative composition

Each 1 mL of solution contains carmellose sodium 5 mg

3. Pharmaceutical Form

Eye drops, solution in single-dose container

Clear and colorless sterile solution.

4. Clinical Particulars

4.1 Therapeutic indications

Tear substitute. Treatment of the symptoms of dry eye.

4.2 Posology and method of administration

Instill 1-2 drops in the affected eye/s 4 times a day or as needed, single use only and should not be reused.

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 carmellose Sodium 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.

Pediatric population

The safety and efficacy of carmellose Sodium 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 pediatric population.

4.3 Contraindication

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

4.4 Special warning 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 Interactions with other medicinal products and other forms of interactions

None known.

For the use of concomitant ocular products, see section 4.2.

4.6 Pregnancy and lactation

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

4.7 Effects on ability to drive and use machine

Mellutear 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.

Post marketing Experience

The following additional adverse reactions have been identified during post marketing use of carmellose Sodium in clinical practice. Because post marketing 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, and ocular hyperemia

Injury, Poisons and Procedural Complications:

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

4.9 Overdose

Accidental overdose will present no hazard.

5. Pharmacological Properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Artificial tears and other indifferent preparations

ATC code: S01XA20

carmellose Sodium has no pharmacological effect.

The excipients in Mellutear 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

boric acid, sodium borate, sodium chloride, potassium chloride (dihydrate), magnesium chloride (hexahydrate), calcium chloride, hydrochloric acid solution (diluted), sodium hydroxide solution (diluted), water for injection

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years from the date of manufacturing.

After first opening: Use immediately.

6.4 Special precautions for storage

Store below 30ºC.

6.5 Nature and contents of container

Mellutear are filled in Blow-Fill-Seal (BFS) technology in plastic tube of 0.3 and 0.4 mL packed in aluminium sachet of 20, 30 and 60 tubes and packed in a paper box of 1 sachet.

7. Manufacturer

Millimed BFS Co., Ltd.

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8. Marketing authorisation number(s)

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9. Date of revision of the text

10 March 2022

Reference 1 : SUMMARY OF PRODUCT CHARACTERISTICS of TEAR MAC SD, 1C 15095/63