<u>เอกสารกำกับยาภาษาอังกฤษ</u>

(เหมือนกันทุกขนาดบรรจุ)

Summary of Product Characteristics

MILTEAR

Hypromellose 0.3% W/V

1. Name of the medicinal product

MILTEAR

Hypromellose 3.0 mg/mL

Eye drops, solution

2. Qualitative and quantitative composition

Each 1 mL of solution contains: Hypromellose 3.0 mg

3. Pharmaceutical Form

Eye drops, solution

Clear, colorless, sterile ophthalmic liquid

4. Clinical Particulars

4.1 Therapeutic indications [2.1], [2.2]

- Hypromellose is used as artificial tears to prevent damage to the cornea in patients with keratoconjunctivitis sicca accompanying rheumatoid arthritis, xerophthalmias or keratitis or during gonioscopy procedures. It is also used to moisten contact lenses and to lubricate artificial eyes. [2.1], [2.2]
- Hypromellose provides immediate relief of dry eye conditions (including dry eye conditions associated with the use of VDUs and TVs, infrequent blinking, certain medical treatments, atmospheric pollution and drying atmospheres e.g., air-conditioning, central heating, wind and sun). [2.1]

4.2 Posology and method of administration [1.2], [2.2], [3.2], [4.2], [5.1], [9.2], [10.1]

Wash your hands before use. [1.2]

The recommended dosage for adults, children and elderly is one or two drops topically instilled into the eye three times daily as needed, or as directed by a physician.

For package sizes of 0.3, 0.4, and 0.5 ml, discard immediately and do not reuse if instillation is complete.

For package sizes of 0.8 and 1 ml, the product should be closed-tight, stored below 30°C after opening, and used within 24 hours after the first opening.

Apply a few drops to each lens before insertion.

Method of administration: For ocular use only.

If you are using in combination with another eye drops medicine, wait 5-15 minutes before applying the second eye drops.

Do not use this product if the solution becomes cloudy or changes color. [5.1]

4.3 Contraindication [1.3], [2.3]

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

4.4 Special warning and precautions for use [1.4], [2.4], [4.3],

- May cause transient mild stinging or temporary blurred vision. If irritation persists or worsens, or headache, eye pain, vision changes or continued redness occur, patients should discontinue use and consult a physician or pharmacist (see section 4.8)

- In order to preserve the sterility, the dropper should not be allowed to touch any part of the eye or any other surface. (Lebel warning: Do not touch any part of the eye with dropper).

4.5 Interactions with other medicinal products and other forms of interactions [2.5]

Hypromellose prolongs the contact time of topically applied drugs commonly used in ophthalmology.

4.6 Pregnancy and lactation [2.6], [5.3]

Fertility

Studies have not been performed to evaluate the effect of topical ocular administration of Hypromellose on fertility. Hypromellose is a pharmacologically inert compound and it would not be expected to have any effect on fertility.

Pregnancy

There are no or limited amount of data from the use of ophthalmic Hypromellose in pregnant women. Systemic exposure to Hypromellose following topical ocular administration is negligible and the product has no pharmacological properties.

Lactation

It is unknown whether topical Hypromellose/metabolites are excreted in human milk. No effects on the breastfed newborn/infant are anticipated since the systemic exposure of the breast-feeding women to Hypromellose is negligible. In addition to this, Hypromellose is pharmacologically inert.

4.7 Effects on ability to drive and use machine [2.7], [5.4]

May cause transient blurring of vision on instillation. Do not drive or operate hazardous machinery unless vision is clear.

4.8 Undesirable effects [2.8], [4.4]

The following adverse reactions have been reported following administration of Hypromellose. Frequency cannot be estimated from the available data:

Eye disorder:

- transient mild stinging or vision blurred
- eye pain
- foreign body sensation in eyes
- eye irritation
- ocular hyperemia

4.9 Overdose [2.9], [4.5]

Due to the characteristics of this preparation, no toxic effects are to be expected with an ocular overdose of this product, nor in the event of accidental ingestion of the contents of one bottle.

5. Pharmacological Properties

5.1 Pharmacodynamic properties [2.10], [6.1], [7.1]

Pharmacotherapeutic group: Ophthalmologicals: other ophthalmologicals

ATC code: SO1XA20

Hypromellose is a soothing emollient solution with properties and uses similar to those of methylcellulose. Its advantages over methylcellulose are that mucilages of Hypromellose have greater clarity and fewer undispersed fibers are usually present. It prolongs the action of medicated eye drops and is used as artificial tears to prevent damage to the cornea in dry eye syndromes.

5.2 Pharmacokinetic properties [2.11], [4.6]

Not applicable to topical (ophthalmic) preparations.

Hypromellose is an inert substance. It has no pharmacological activity and not absorbed systemically. Hence, the pharmacokinetic properties have not been studied.

5.3 Preclinical safety data [2.12], [4.7]

Hypromellose is an inert substance and is not expected to be absorbed systemically. Hence, although no systemic toxicity studies have been conducted it is not expected to demonstrate any systemic toxicity or to have any effect on reproductive processes.

Similarly, no specific local ocular toxicity or irritation studies have been conducted, however, no adverse effects are anticipated. Indeed, Hypromellose ophthalmic solution is used as a control in some ophthalmic drug studies because of the acknowledged low level of toxicity.

6. Pharmaceutical Particulars

6.1 List of excipients

Boric acid, Sodium borate, Sodium chloride, Potassium chloride, Magnesium chloride, Calcium chloride, Zinc sulphate, Hydrochloric acid, Sodium hydroxide, Water for injection

6.2 Incompatibilities [2.13], [4.8]

Not know

6.3 Shelf life

3 years

6.4 Special precautions for storage

To close, press tab down over containing tip and twist.

Store below 30°C

For package sizes of 0.3, 0.4, and 0.5 ml, discard immediately and do not reuse if instillation is complete.

For package sizes of 0.8 and 1 ml, the product should be closed-tight, stored below 30°C after opening, and used within 24 hours after the first opening.

6.5 Nature and contents of container

MILTEAR are filled in LDPE plastic tube of 0.3, 0.4, 0.5, 0.8 and 1 mL packed in aluminium sachet of 5 and 10 tubes and in a paper box of 1, 2, 3, 6 and 10 sachets.

7. Manufacturer

Millimed BFS Co., Ltd.
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8. Marketing authorisation number(s)

XXXXXXXX

9. Date of first authorisation/renewal of the authorization

XX.XX.XX

10. Date of revision of the text

27 May 2022

Reference 1: Package Insert of Genteal®. Update August 2016
Reference 2: SmPC of Hypromellose Eye Drops BP. Update 26-Aug-2020
Reference 3: Package Insert of Natear®.
Reference 4: SmPC of Isopto Plain 0.5% eye drops, solution. Update 12-Feb-2020
Reference 5: SmPC of Tear Naturale Single Dose Eye drops. Update 12-Feb-2020
Reference 6: WHOCC-ATC_DDD Index of Hypromellose. Update 17-Dec-2020
Reference 7: Martindale 39th edition of Hypromellose. Update June 2017
Reference 8: Information of Blink contact®. Update May 2015
Reference 9: Package Insert of Refresh contact®. Update June 2013
Reference 10: Package leaflet of HYPROMELLOSE EYE DROPS BP. Update June 2020
Reference 11: Leaflet of LACRISERT® from US.FDA Drug approved. Update May 2007