เอกสารกำกับยาภาษาอังกฤษ

(เหมือนกันทุกขนาดบรรจุ)

Summary of Product Characteristics

TRANCELTEAR

Dextran 70 0.1% and Hypromellose 0.3%

Preservative-free

1. Name of the medicinal product

TRANCELTEAR

Dextran 70 0.1% and Hypromellose 0.3%

Eye drops, solution

2. Qualitative and quantitative composition

Each mL contains: -

Dextran 70	1	mg
Hypromellose	3	mg

For the full list of excipients, see section 6.1.

3. Pharmaceutical Form

Eye drops, solution

Clear and colorless sterile solution

4. Clinical Particulars

4.1 Therapeutic indications [1.1, 2.1]

For the temporary relief of discomfort due to minor irritations of the eye or to exposure to wind or sun.

Tranceltear is a lubricant and artificial tear for treatment of dry eye and other ocular irritation syndromes associated with deficient tear or mucous secretion.

4.2 Posology and method of administration

(1) Posology [1.2]

Adults, children and the elderly:

One or two drops as required or directed instilled into the affected eyes.

(2) Method of administration [1.2]

For ocular use

Patients must not use this product if the solution becomes cloudy or changes color. To avoid contamination, do not touch tip of container to any surface.

Dosage and administration

1. Ensure that the container is not opened.
2. Open the container by twist the lid.
3. Directed instilled one or two drops into the affected eyes as required.

4.3 Contraindication [1.3]

Hypersensitivity to dextran 70, hypromellose or to any of the excipients.

4.4 Special warning and precautions for use [1.4]

• For ocular use only. Not for injection or ingestion.

• If patients experience headache, eye pain, vision changes, irritation of the eyes, persistent redness, or if the condition worsens or persists for more than 3 days, they are to discontinue use and consult their doctor.

4.5 Interactions with other medicinal products and other forms of interactions [1.5]

If more than one topical ophthalmic medicinal product is being used, the medicines must be administered at least 5 minutes apart. Eye ointments should be administered last.

4.6 Pregnancy and lactation [1.6]

Fertility

There is no adequate data regarding the impact of Tranceltear on fertility. Dextran 70 and hypromellose are pharmacologically inert compounds or generally classified as non-toxic and non-irritating. Therefore, no effects on fertility are anticipated.

Pregnancy

There is no adequate data from the use of Tranceltear in pregnant women. Dextran 70 and hypromellose are pharmacologically inert compounds or generally classified as non-toxic and non-irritating; therefore, no adverse effects during pregnancy are anticipated. These components are not expected to be absorbed systemically, to demonstrate any systemic toxicity or to have any effect on reproduction or embryofetal development. Tranceltear can be used during pregnancy.

Breast-feeding

There is no adequate data regarding the impact of Tranceltear Eye drops, Solution on lactation. Dextran 70 and hypromellose are pharmacologically inert compounds or generally classified as non-toxic and non-irritating therefore, no adverse effects during breast-feeding are anticipated. It is unknown whether dextran 70, hypromellose or any of the components are excreted in human milk. Nonetheless, discontinuation of product use during breast-feeding is not considered necessary.

4.7 Effects on ability to drive and use machine [1.7]

Tranceltear has no or negligible influence on the ability to drive or use machines. As with any eye drops, temporary blurred vision or other visual disturbances may affect the ability to drive or use machines. If blurred vision occurs at instillation, the patient must wait until the vision clears before driving or using machines.

4.8 Undesirable effects [1.8]

4.8.1. Summary of the safety profile

The most frequently occurring adverse reaction during clinical trials was vision blurred.

4.8.2. Tabulated list of adverse reactions

The following adverse reactions are classified according to the following convention: very common (≥ 1/10), common (≥ 1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000), very rare (<1/10,000), or not known (cannot be estimated from the available data). Within each frequency-grouping, adverse reactions are presented in order of decreasing seriousness. The adverse reactions were obtained from clinical trials and post marketing spontaneous reports.

System Organ Classification	**MedDRA Preferred Term (v.19.0)**
Immune system disorders	*Not known:* hypersensitivity
Nervous system disorders	*Uncommon:* headache
Eye disorders	*Very common:* vision blurred *Common:* dry eye (residual), eyelid disorder, abnormal sensation in eye, foreign body sensation in eyes, ocular discomfort. *Uncommon:* photophobia, hypoaesthesia eye, eye pruritus, eye irritation, ocular hyperaemia. *Not known:* erythema of eyelid, eye swelling, eye pain, eye discharge, eyelid margin crusting, lacrimation increased.

General disorders and administration site conditions	*Uncommon:* discomfort (skin)

4.9 Overdose [1.9]

• No case of overdose has been reported.

• An overdose of Tranceltear can easily be washed out of the eye with lukewarm tap water.

5. Pharmacological Properties [1.10]

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: Artificial Tears

ATC Code: S01XA20.

The combination of Dextran 70 and hypromellose in an aqueous presentation provides a soothing lubricant preparation for the relief of dry eye syndrome associated with deficient tear secretion or deficient mucous.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6. Pharmaceutical Particulars

6.1 List of excipients

Sodium hydrogen carbonate

Sodium chloride

Potassium chloride

Magnesium chloride (hexahydrate)

Calcium chloride (dihydrate)

Hydrochloric acid solution (diluted)

Sodium hydroxide solution (diluted)

Water for injection

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years (unopened).

6.4 Special precautions for storage

Store below 30°C.

Do not refrigerate.

Keep container tightly closed.

Discard container 12 hours after opening.

6.5 Nature and contents of container

Tranceltear are filled in LDPE plastic tube of 0.3 and 0.8 mL packed in aluminium sachet and in a paper box of 30 and 60 tubes

7. Marketing authorisation holder

Millimed BFS Co., Ltd.

174, 179 Moo 8, Pha Ngam, Wiang Chai,

Chiang Rai 57210

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8. Marketing authorization number(s)

2A 15001/65

9. Date of first authorization/renewal of the authorization

27 January 2022

10. Date of revision of the text

14 September 2022