Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Tears Naturale eye drops, solution (Dextran 70 0.1% w/v, Hypromellose 0.3% w/v)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Dextran 70 0.1% w/v
Hypromellose 0.3% w/v
Also contains Benzalkonium Chloride Solution 0.01% w/v.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution
A slightly viscous, clear and almost colourless solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As a lubricant and artificial tear in dry eye and other ocular irritation syndromes associated with deficient tear or mucous secretion.

4.2 Posology and method of administration

Adults, children and the elderly:
One or two drops as required or directed instilled into the conjunctival sac.

Method of administration
For ocular use

Patients must not use this product if the solution becomes cloudy or changes colour.

To avoid contamination, do not touch tip of container to any surface. Replace cap after using.

Remove the loose collar from the cap when the bottle is first opened to avoid eye injury.

4.3 Contraindications

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

4.4 Special warnings and precautions for use

- For ocular use only. Not for injection or ingestion.
- Tears Naturale contains benzalkonium chloride which may cause eye irritation and is known to discolour soft contact lenses. Contact with soft contact lenses is to be avoided. Patients should be advised to remove their contact lenses prior to the application of Tears Naturale and wait at least 15 minutes before reinsertion.
- 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 a doctor.

4.5 Interaction with other medicinal products and other forms of interactions

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 Fertility, pregnancy and lactation

Fertility
There is no adequate data regarding the impact of Tears Naturale on fertility. All of the components are pharmacologically inert compounds or generally classified as non-toxic and non-irritating (See Section 5.3). Therefore, no effects on fertility are anticipated.

Pregnancy
There is no adequate data from the use of Tears Naturale in pregnant women. All of the components are pharmacologically inert compounds or generally classified as non-toxic and non-irritating (See Section 5.3); therefore, no adverse effects during pregnancy are anticipated. Tears Naturale can be used during pregnancy.

Breast-feeding
There is no adequate data regarding the impact of Tears Naturale Eye drops, Solution on lactation. All of the components are pharmacologically inert compounds or generally classified as non-toxic and non-irritating (See Section 5.3); therefore, no adverse effects during breast-feeding are anticipated. Tears Naturale can be used during breast-feeding.

4.7 Effects on ability to drive and use machines

Tears Naturale 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

a. Summary of the safety profile

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

b. 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

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

- No case of overdose has been reported.
- An overdose of Tears Naturale can easily be washed out of the eye with lukewarm tap water.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: Artificial Tears
ATC Code: S01X A20

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

Benzalkonium chloride solution
Disodium edetate
Sodium chloride
Potassium chloride
Sodium hydroxide and/or Hydrochloric acid, concentrated (for pH adjustment)
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Unopened: 3 years.
Any unused contents should be discarded 4 weeks after first opening.

6.4 Special precautions for storage

Do not store above 25°C.
Do not refrigerate.
Keep container tightly closed.
Discard 4 weeks after opening.

6.5 Nature and contents of container

15 ml Drop-Tainer - Low density polyethylene bottle and plug with polypropylene cap.

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

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Alcon Laboratories Ireland Limited
Cork Business & Technology Park
Model Farm Road
Cork
Ireland

8 MARKETING AUTHORISATION NUMBER

PA2274/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13 March 1980

Date of last renewal: 13 March 2010

10 DATE OF REVISION OF THE TEXT

December 2019