

IRISH MEDICINES BOARD ACTS 1995 AND 2006

MEDICINAL PRODUCTS(CONTROL OF PLACING ON THE MARKET)REGULATIONS,2007

(S.I. No.540 of 2007)

PA0290/075/001

Case No: 2064762

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Alcon Laboratories (UK) Ltd

Pentagon Park, Boundary Way, Hemel Hempstead, Hertfordshire HP2 7UD, England

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Tears Naturale Single Dose

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **09/02/2010**.

Signed on behalf of the Irish Medicines Board this

A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Tears Naturale Single Dose

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml of Tears Naturale Single Dose contains:

Dextran 70	1.0 mg
Hypromellose	3.0 mg

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution

A clear, colourless solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Tear substitute for the treatment of moderate to severe dry eye, including kerato-conjunctivitis sicca.

4.2 Posology and method of administration

Instill 1 or 2 drops in the affected eye(s) as needed, or as prescribed by the physician. These drops may be used by both adults and children.

4.3 Contraindications

Hypersensitivity to any of the components of the medication.

4.4 Special warnings and precautions for use

Only for topical ophthalmic use.

If patients experience eye pain, changes in vision, persistent redness or irritation of the eyes, or if the condition worsens or persists, they are to discontinue use and consult a doctor.

If more than one locally acting eye preparation is used, the products shall be given with an interval of at least 10-15 minutes.

4.5 Interaction with other medicinal products and other forms of interaction

Interactions of Tears Naturale Single Dose with other medications have not been specifically evaluated.

4.6 Pregnancy and lactation

Information on the use of these eye drops during pregnancy and lactation is not available.

4.7 Effects on ability to drive and use machines

As with any ocular medication, if transient blurred vision occurs at instillation, the patient should wait until the vision clears before driving or using machinery.

4.8 Undesirable effects

Tears Naturale Single Dose was administered in clinical studies involving 89 patients. The most frequently reported treatment-related undesirable effects were blurred vision (4.5%) and ocular discomfort (3.4%).

The following undesirable effects assessed as definitely, probably, or possibly related to treatment were reported during clinical trials with Tears Naturale Single Dose. Their incidence was common (1.0% to 10.0%, maximum observed actual incidence of 4.5%) and no undesirable effects were reported at an incidence less than 1% (uncommon) or 0.1% (rare). No systemic undesirable effects were reported as related to treatment with Tears Naturale Single Dose.

Ocular Effects

Common: blurred vision (4.5%), ocular discomfort (burning and/or stinging) (3.4%), ocular fatigue (1.1%), foreign body sensation (1.1%), ocular hyperemia (1.1%), ocular pruritus (1.1%).

Clinical Practice

The following events have been identified during postmarketing use of BION TEARS (identical product to Tears Naturale Single Dose). Since these are reported voluntarily from a population of unknown size, exact determination of frequency cannot be made. The most frequently reported events include ocular discomfort, ocular irritation, ocular hyperemia and blurred vision.

4.9 Overdose

If overdose with Tears Naturale Single Dose occurs, flush the eye with warm water.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Tears Naturale Single Dose is an unpreserved physiological tear product, which contains the ionic components of the human tear: calcium, magnesium, sodium, potassium, zinc, bicarbonate and chloride ions. Tears Naturale Single Dose also contains the DUASORB system, which consists of two water-soluble polymers: Dextran 70 and hypromellose. The system provides a lubricant and emollient effect to the cornea. The surface tension and viscosity of Tears Naturale Single Dose are similar to those of natural tears.

An animal model study demonstrated that a tear solution with physiologic electrolyte composition, including bicarbonate, can provide an environment for the cornea which is conducive to recovery from epithelial damage. This suggests that artificial tears containing bicarbonate may also be of benefit in the treatment of the compromised ocular surface epithelium of dry eye patients. Results of an open-label clinical trial in patients with keratoconjunctivitis sicca showed that Tears Naturale Single Dose provided objective improvement in ocular surface desiccation, cell pathology and symptomatic complaints as compared with a control formulation without bicarbonate.

5.2 Pharmacokinetic properties

The pharmacokinetics of Dextran 70 and hypromellose have not been studied in this product. Due to the high molecular weights of these polymers, penetration into the cornea and conjunctiva is expected to be low.

5.3 Preclinical safety data

The preclinical safety of Tears Naturale Single Dose was demonstrated in an exaggerated treatment regimen with 12 applications of the product to rabbits' eyes over a 5.5-hour period. Prior to instillation, the test samples had been opened, stored at room temperature for 10 days, followed by storage at 45° C for 50 hours, in order to increase the pH to approximately 8.8. Under this exaggerated treatment regimen, the product was found to be well tolerated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride
Potassium chloride
Calcium chloride (dihydrate)
Magnesium chloride (hexahydrate)
Zinc chloride
Sodium hydrogen carbonate
Carbon dioxide (to adjust pH)
Purified water

6.2 Incompatibilities

Not applicable

6.3 Shelf Life

2 years.

Once the pouch has been opened, any unused vials should be stored in the open pouch. Tears Naturale Single Dose should not be used for longer than four days after first opening the pouch. A vial should be discarded immediately after first use.

6.4 Special precautions for storage

Do not store above 25°C.
Do not freeze.
Once the pouch has been opened, any unused vials should be stored in the opened pouch.

6.5 Nature and contents of container

28 x 0.4 ml dose LDPE containers.
The package contains seven aluminium overwrap, each of which contains four unit dose containers.

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

Ensure that the container is intact before use.

Separate one container. To open, completely TWIST off tab; do not PULL off.

Do not touch the tip of the container to any surface in order to avoid contamination of the contents.

The solution should not be used if it has changed colour or has become cloudy.

Once the pouch has been opened, any unused vials should be stored in the open pouch.

Tears Naturale Single Dose should not be used for longer than four days after first opening the pouch.

A vial should be discarded immediately after first use.

7 MARKETING AUTHORISATION HOLDER

Alcon Laboratories (UK) Ltd
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United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA 290/75/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 05 March 2004

Date of last renewal: 05 March 2009

10 DATE OF REVISION OF THE TEXT

February 2010