Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Minims Artificial Tears 0.35% w/w + 0.44% w/w Eye Drops, Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Hyetellose Ph. Eur. 0.44 % w/w and sodium chloride Ph. Eur. 0.35 % w/w.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution
Sterile, single use eye drops, solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the relief of dry eye syndromes associated with deficient tear secretion.

4.2 Posology and method of administration

One or two drops instilled into the affected eye three or four times daily, or as often as is required.

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

If irritation persists or worsens or continued redness occurs, discontinue use and consult a physician or ophthalmologist.

Keep out of reach of children.

4.5 Interaction with other medicinal products and other forms of interactions

None known.

4.6 Fertility, pregnancy and lactation

There is no evidence of safety of this product in human pregnancy. If therapy with artificial tears is needed in pregnancy this preparation can be used if recommended by a physician and it is considered that the benefits outweigh the possible risks.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

May cause transient mild stinging or temporarily blurred vision.

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

Overdose would not be expected to produce symptoms.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Artificial tears and other indifferent preparations.
ATC code: S01XA20

The viscolising properties of hyetellose combined with sodium chloride act as a lubricating agent for dry eyes.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

No adverse safety issues were detected during the development of this formulation. The active ingredients are well-established in clinical ophthalmology.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Purified water
Borax
Boric acid

6.2 Incompatibilities

Not applicable

6.3 Shelf life

Unopened: 18 months

6.4 Special precautions for storage

Do not store above 25°C. Do not freeze. Store in the original package.

6.5 Nature and contents of container

A sealed conical shaped polypropylene container fitted with a twist and pull off cap made from Ph. Eur. grade polypropylene for containers and closures for parenteral and ophthalmic preparations. Each Minims unit is overwrapped in an individual polypropylene/paper pouch. Each container holds approximately 0.5 ml of solution. There are 20 minims units in every carton.

6.6 Special precautions for disposal

For single use only.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Bausch + Lomb Ireland Limited
3013 Lake Drive
Citywest Business Campus
Dublin 24
D24 PPT3
Ireland

8 MARKETING AUTHORISATION NUMBER

PA23259/013/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23 March 1992

Date of last renewal: 23 March 2007

10 DATE OF REVISION OF THE TEXT

June 2022