

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Minims Artificial Tears

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Clear, colourless, sterile eye drops containing hyetellose 0.44% w/w and sodium chloride 0.35% w/w.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Sterile single-use eye drop.

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.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

There is no evidence of safety of the drug in human pregnancy but it has been in wide use for many years without apparent ill consequence. If drug therapy 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 the Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard

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 have been shown to increase the tear break-up time in animal models, whilst also acting 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

18 months.

6.4 Special precautions for storage

Store below 25°C. Do not freeze. Protect from light.

6.5 Nature and contents of container

A sealed conical shaped polypropylene container fitted with a twist and pull off cap. Each Minims unit is overwrapped in an individual polypropylene/paper pouch.

6.6 Special precautions for disposal

Each Minims unit should be discarded after a single use.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

PL 03468/0067

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

11 January 1990

10 DATE OF REVISION OF THE TEXT

30/10/2018