Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Geltears 0.2 % w/w carbomer eye gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

0.2% w/w carbomer .
Excipients contains 0.01% w/w Benzalkonium chloride.

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Eye gel.
Homogeneous, colourless, gel.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Substitution of tear fluid in the management of dry eye conditions, including keratoconjunctivitis sicca and unstable tear film.

4.2 Posology and method of administration

Adults (including the elderly) and children and adolescents aged to 18 years:
One drop to be instilled into the conjunctival fold of each affected eye 3 - 4 times daily or as required, depending on the degree of discomfort.
The safety and efficacy of GelTears in children and adolescents at the posology recommended for adults has been established by clinical experience, but no clinical trial data are available

4.3 Contraindications

Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Blurred vision can occur if too much gel is instilled at one time, or if the gel is used too frequently. This effect can last for up to an hour. Recovery can be aided by blinking vigorously for a few seconds. If this fails, the lower eyelid should be manipulated until the gel returns to the lower fornix and normal vision is restored.

Contact lenses should be removed during treatment with GelTears.

4.5 Interaction with other medicinal products and other forms of interactions

No significant interactions have been reported.

4.6 Fertility, pregnancy and lactation

Safety for use in pregnancy and lactation has not been established, therefore, GelTears should not be used in these circumstances.

4.7 Effects on ability to drive and use machines

As with other ophthalmic preparations, transient blurring of vision may occur on instillation. If affected, the patient should be advised not to drive or operate hazardous machinery until normal vision is restored.

4.8 Undesirable effects

Corneal irritation due to benzalkonium chloride could possibly occur with prolonged use.
Further undesirable effects might be eye erythema, eye redness and visual disturbance.

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

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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

GelTears contains Carbomer 980, a hydrophilic, high molecular weight polymer of carboxyvinylic acid. The gel forms a transparent lubricating and moistening film on the surface of the eye. The preparation has a pH similar to those found in the normal tear film and is slightly hypotonic with respect to tears. GelTears relieves the symptoms of irritation linked with dry eye syndromes and protects the cornea against drying out.

The use of vital stains has provided objective evidence that the corneal and conjunctival epithelial lesions associated with dry eye syndromes show improvement on treatment with GelTears. The gel remains on the surface of the eye for longer than low viscosity artificial tears and hence, less frequent application is required.

5.2 Pharmacokinetic properties

No human pharmacokinetic studies are available; however, absorption or accumulation in tissues is likely to be negligible due to the high molecular weight of the active ingredient.

5.3 Preclinical safety data

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium chloride
Water for injection
Sorbitol
Sodium hydroxide

6.2 Incompatibilities

Not applicable

6.3 Shelf life

Unopened: 3 years
Once opened: 28 days

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

Sterile ophthalmic gel presented in 10 g plasticised, lacquered aluminium tubes, closed with a tamper evident high density polyethylene cap. Each tube is individually packaged with a patient information leaflet.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER

PA23259/006/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 07 February 1997

Date of last renewal: 07 February 2007

10 DATE OF REVISION OF THE TEXT

July 2022