Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Vidisic Preservative Free Single Dose Unit

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Carbomer 0.2% w/w.

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye gel.
Colourless, clear, aqueous eye gel, without visible particles for single use.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

This medicinal product is for symptomatic relief of dry eyes associated with the sicca syndrome.

Vidisic Preservative Free Single Dose Unit is indicated in adults and children.

4.2 Posology and method of administration

Posology
One drop into the conjunctive sac 3-5 times per day.

Children and adolescents aged to 18 years:
The safety and efficacy of Vidisic eye gel in children and adolescents at the posology recommended in adults has been established by clinical experience, but no clinical trial data are available.

Method of administration
For ocular use.

4.3 Contraindications

Use in patients hypersensitive to the active substance or to any of the excipients listed in section 6.1.
Should not be used for undiagnosed conjunctivitis.

4.4 Special warnings and precautions for use

Wearers of contact lenses should remove their lenses before Vidisic is instilled and should wait for l5 minutes before they insert them again.

Discontinuation of the treatment is advised in cases of irritation of the eyes, persistent redness, or if the condition worsens or persists.

4.5 Interaction with other medicinal products and other forms of interactions

Vidisic Preservative Free Single Dose Unit may prolong the contact-time of topically applied drugs in ophthalmology.

Concomitant ocular medication should be administered 15 minutes prior to the instillation of Vidisic Preservative Free Single Dose Unit.

4.6 Fertility, pregnancy and lactation

Pregnancy
Safety of Carbomer for use in pregnancy has not been established. Vidisic gel should not be used in pregnancy unless it is considered by the patient's physician that the benefits of treatment outweigh the risks.

Breast-feeding
Safety of Carbomer for use in lactation has not been established.
Vidisic gel should not be used in lactation unless it is considered by the patient's physician that the benefits of treatment outweigh the risks.

Fertility
Safety of Carbomer for use in pregnancy has not been established.

4.7 Effects on ability to drive and use machines

Even when administered as directed, this product may cause a transient blurring in vision and patients should exercise caution when driving or operating machinery.

4.8 Undesirable effects

Vidisic gel is generally well tolerated. The following adverse reactions have been reported

Eye disorders
Rare (≥1/10,000 to <1/1,000):
Eye irritation, Eye pain, Eye swelling, Ocular hyperemia, keratitis, conjunctivitis.

Very rare (<1/10,000)
Cases of corneal calcification have been reported very rarely in association with the use of phosphate containing eye drops in some patients with significantly damaged corneas.

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
Website: www.hpra.ie

4.9 Overdose

Not relevant.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code: S01XA20

Vidisic Preservative Free Single Dose Unit gel is a substitute for lacrimal fluid. The gel structure of carbomer retains moisture, which is destroyed by the salts in tear fluid, releasing moisture.

5.2 Pharmacokinetic properties

Not relevant.

5.3 Preclinical safety data

Not relevant.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitol (E420)
Disodium phosphate dodecahydrate
Sodium hydroxide
Water for injections

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

For single use only. Discard immediately after use.

6.4 Special precautions for storage

Do not store above 25°C. Keep container in the outer carton.

6.5 Nature and contents of container

Low-density, polyethylene, single-dose container.

Pack size: 0.6 ml x 20, 30, 60, or 120 units.

Not all pack sizes may be marketed

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Bausch + Lomb Ireland Limited
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8 MARKETING AUTHORISATION NUMBER

PA23259/008/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14 December 2001

Date of last renewal: 14 December 2006

10 DATE OF REVISION OF THE TEXT