Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Vidisic 0.2 % w/w eye gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

The product contains carbomer 0.2 % w/w

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye gel.
Sterile, colourless, clear, aqueous eye gel, without visible particles.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For symptomtic relief of dry eyes associated with the sicca syndrome.

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 0.2 % w/w 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.

4.3 Contraindications

Hypersensitivity 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 15 minutes before they insert them again.

Intolerance reactions to one of the ingredients may be seen in isolated cases. Vidisic gel contains cetrimide as a preservative which, particularly when used frequently or for a long period, may cause ocular irritation (burning, redness, foreign body sensation) and may damage the corneal epithelium. Preservative-free medicinal products should therefore be preferred for long-term treatment of chronic keratoconjuctivitis sicca.

4.5 Interaction with other medicinal products and other forms of interaction

Vidisic 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.

Vidisic should always be the last medication to be administered.

4.6 Fertility, pregnancy and lactation

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

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 rarely:

Local burning, irritation, stinging, swelling, redness and inflammation of the eye.

If Vidisic Gel causes you any problems, tell your doctor or pharmacist.

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 relevant.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Ophthalmologicals: other ophthalmologicals
ATC code: S0lX A20

Mechanism of action
Vidisic Gel is a substitute for lacrimal fluid. The gel structure has high water-binding capability and forms a stable hydrophilic film that adheres to the ocular surface.

5.2 Pharmacokinetic properties

Absorption
In pharmacokinetic studies, radioactive carbomer was administered to rats. It could be shown that only a small amount of carbomer is absorbed.
As systemic absorption of ocular administration is low, this is not of relevance to the prescriber.

Distribution
Following single administration, 0.75% of the administered dose was detected as carbon dioxide in the expired air, and 0.63% in the urine. The major proportion of carbomer (92%) was detected unchanged in the faeces 24 hours after intake.

5.3 Preclinical safety data

The LD50 value could not be ascertained due to the low toxicity. In studies on rats, no deaths were observed at a concentration of 625 mg/kg carbomer.

Oral doses of 0.5, 1.0 and 3.0 g/kg bodyweight were administered to pregnant rats during a period between days 6 and 13 of gestation. No pathological alterations were seen in the embryos.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cetrimide
Sorbitol
Water for injections
Sodium hydroxide

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years as packaged for sale.

Discard tube 1 month after first opening.

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

Polyfoil (HDPE-lined, aluminium, co-polymer layered) tube with HDPE cap.

Pack size: 10 g

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

Avoid contamination during use. Sterile until opened.

Hold the tube in an upright position so that a small drop, which falls easily from the tip, is formed.

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
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Ireland

8 MARKETING AUTHORISATION NUMBER

PA23259/008/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11th August 1993

Date of last renewal: 11th August 2008

10 DATE OF REVISION OF THE TEXT

November 2022