

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.

Product imported from Germany:

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

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

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

4.2 Posology and method of administration

4.2.1 Dosage

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

4.2.2 Administration

For ocular use

4.3 Contraindications

Use in patients hypersensitive to the constituents. 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 keratoconjunctivitis 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.

4.9 Overdose

Not relevant.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group:
Ophthalmologicals: other ophthalmologicals
ATC code: S01X A20

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

In pharmacokinetic studies, radioactive carbomer was administered to rats. It could be shown that only a small amount of carbomer is absorbed. 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.

As systemic absorption of ocular administration is low, this is not of relevance to the prescriber.

5.3 Preclinical safety data

The LD50 value could not be ascertained due to the low toxicity. In studies on rats, no deaths

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

The shelf life expiry date of this product is the date shown on the container and outer package of the product in the country of origin.
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

Tube with 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.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/309/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11th October 2013

10 DATE OF REVISION OF THE TEXT