SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Viscotears Single Dose Unit 2.0mg/g Eye Gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

2.0mg/g Carbomer (polyacrylic acid)

For a full list of excipients, see section 6.1 List of excipients

3 PHARMACEUTICAL FORM

Eye Gel

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

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

4.2 Posology and method of administration

For ocular use.

Adults:
1 drop 3 - 4 times daily or as required, depending upon the severity of the disease

Elderly:
No dosage amendment is necessary in the elderly

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

Viscotears SDU contains a sterile gel until the original closure is broken. The tip of the container should not come into contact with any surface including the eye, as this may cause injury to the eye

Viscotears Single Dose Unit should be used immediately after opening and discarded after use.

4.3 Contraindications

Patients with known hypersensitivity to carbomer (polyacrylic acid) or to any of the excipients.

4.4 Special warnings and precautions for use

- For ocular use only
- If patients experience eye pain, vision changes, irritation of the eyes, persistent redness or if the condition worsens or persists, they are to discontinue use and consult their doctor.
- Although the product contains no preservative, contact lenses should not be worn during instillation of the drug due to the viscosity. After instillation there should be an interval of at least 15 minutes before reinsertion.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed

No clinically relevant interactions have been described.

In case of any additional local ocular treatment (eg glaucoma therapy) there should be an application interval of at least 5 minutes between the two medications, Viscotears Single Dose Unit always should be the last medication instilled.

4.6 Pregnancy and lactation

Pregnancy

There are no data from the use of carbomer in pregnant women. However no effects during pregnancy are anticipated, since the systemic exposure to carbomer is expected to be negligible. Additionally, carbomer is an inactive ingredient that exerts a surface protective effect.

Lactation
It is unknown whether carbomer or any of the components are excreted in human milk.
However no effects on the breastfed newborn/infant are anticipated since the systemic exposure of the breast-feeding woman to carbomer is expected to be negligible. Additionally, carbomer is an inactive ingredient that exerts a surface protective effect.
Administration during pregnancy and lactation is not recommended, except for compelling reasons.

Fertility
There are no available data on the use of this medicine affecting male or female fertility.

4.7 Effects on ability to drive and use machines

Viscotears Liquid Gel has no or negligible influence on the ability to drive and use machines.

Viscotears may temporarily influence the visual acuity. Patients with blurred vision driving a vehicle or operating machines should be alerted to the possibility of impaired reactions.

The patient must wait until the vision clears before driving or using machinery.

4.8 Undesirable effects

Summary of the safety profile
In clinical trials, the most frequently reported adverse reactions were blurred vision occurring in 11% of patients and eyelid margin crusting occurring in 7.79% of patients.

The following adverse reactions have been reported during clinical trials with Carbomer 2mg/g, 3mg/g and are classified according to the following convention: very common (≥ 1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000), very rare (<1/10,000), or not known (cannot be estimated from the available data). Within each frequency-grouping, adverse reactions are presented in order of decreasing seriousness.

System Organ Classification	Adverse reactions
Eye disorders	*Very common:* vision blurred *Common*: ocular discomfort, eyelid margin

	crusting, eye irritation *Uncommon*: periorbital oedema, conjunctival oedema, eye pain, eye pruritus, ocular hyperaemia, lacrimation increased
Skin and subcutaneous tissue disorders	*Uncommon*: dermatitis contact

Additional adverse reactions identified from post-marketing surveillance include the following.

Frequencies cannot be estimated from the available data.

System Organ Classification	Adverse reactions
Immune system disorders	*Not known:* Hypersensitivity

Reporting of suspected adverse reactions
Reporting of 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 at www.mhra.gov.uk/yellowcard

4.9 Overdose

Due to the characteristics of this preparation, no toxic effects are to be expected with an ocular overdose of this product, nor in the event of accidental ingestion of the contents of one tube.

Although this is unlikely to occur, should patients experience any untoward symptoms after applying too much Viscotears or accidental ingestion, treatment should be symptomatic.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Viscotears Single Dose Unit is a preservative-free liquid gel containing carbomer. After local instillation it spreads rapidly over the conjunctiva and cornea and forms a lubricating film with prolonged contact time.

The retention times of Viscotears Liquid Gel (a similar product containing a preservative) and a conventional tear substitute based on polyvinylalcohol were studied in 30 healthy volunteers with fluorescein staining. The retention time of Viscotears Liquid Gel was approximately 16 minutes compared with approximately 2 minutes for the conventional artificial tears eye drops. Tear film stability was maintained for a period of up to 6 hours. Data of clinical studies on healthy volunteers, patients with dry eye and patients in intensive care or during operation suggest evidence that Viscotears Liquid Gel improves tear film stability and prolongs tear break-up time (BUT

5.2 Pharmacokinetic properties

There are no controlled animal or human pharmacokinetic studies available. However, absorption or accumulation in eye tissues can presumably be excluded due to the high molecular weight of polyacrylic acid (4 mio D).

5.3 Preclinical safety data

The results of the preclinical tests do not add anything of further significance to the prescriber.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitol, sodium hydroxide and water for injections.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

For single use only. Use immediately after first opening.

6.4 Special precautions for storage

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

6.5 Nature and contents of container

Transparent LDPE single-dose container containing 0.6ml of gel.
Available in packs of 5, 10, 15, 20 and 30 single dose units

6.6 Special precautions for disposal

Not applicable.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

PL13757/0019

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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01/11/2016