

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1 NAME OF THE MEDICINAL PRODUCT**

Viscotears Liquid Gel.

### **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

2.0mg/g Carbomer (polyacrylic acid).

Excipients: 1 gram of gel contains 0.1mg of Cetrимide (see section 4.4.)

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

### **3 PHARMACEUTICAL FORM**

Eye drops.

### **4 CLINICAL PARTICULARS**

#### **4.1 Therapeutic indications**

Substitute of tear fluid for 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 Liquid Gel in children and adolescents at the posology recommended in adults has been established by clinical experience, but no clinical trial data are available.

Viscotears Liquid Gel 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 and contaminate the gel. Discard four weeks after first opening.

#### **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.
- Viscotears Liquid Gel contains cetrimide which may cause eye irritation and is known to discolour soft contact lenses. Avoid contact with soft contact lenses. Patients must be instructed to remove contact lenses prior to application of Viscotears. 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 Liquid Gel 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 Liquid Gel 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 ( $\geq 1/10$ ), common ( $\geq 1/100$  to  $<1/10$ ), uncommon ( $\geq 1/1,000$  to  $<1/100$ ), rare ( $\geq 1/10,000$  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.

<b>System Organ Classification</b>	<b>Adverse reactions</b>
Eye disorders	<i>Very common:</i> vision blurred <i>Common:</i> ocular discomfort, eyelid margin crusting, eye irritation <i>Uncommon:</i> periorbital oedema, conjunctival

	oedema, eye pain, eye pruritus, ocular hyperaemia, lacrimation increased
Skin and subcutaneous tissue disorders	<i>Uncommon:</i> dermatitis contact

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

Frequencies cannot be estimated from the available data.

<b>System Organ Classification</b>	<b>Adverse reactions</b>
Immune system disorders	<i>Not known:</i> 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](http://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 bottle.

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 Liquid Gel is a 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 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**

Cetrimide, sodium hydroxide, sorbitol and water for injections.

## **6.2 Incompatibilities**

None known.

## **6.3 Shelf life**

Unopened: 36 months

Opened: 28 days

## **6.4 Special precautions for storage**

Do not store above 25°C.

**6.5 Nature and contents of container**

Polyfoil (lamine) tube with cannula and closure containing 10g of liquid gel.

**6.6 Special precautions for disposal**

None stated.

**7 MARKETING AUTHORISATION HOLDER**

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**8 MARKETING AUTHORISATION NUMBER(S)**

PL13757/0020

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06/12/2004

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01/11/2016