

NEW ZEALAND DATA SHEET

Viscotears[®] Carbomer (polyacrylic acid) 0.2% Liquid Eye Gel

Description and composition

Each gram of eye gel contains 2 mg of carbomer (polyacrylic acid, Carbopol[®] 980 NF).

For a full list of excipients, see List of excipients.

Pharmaceutical form

Eye gel.

Viscotears is a sterile, translucent and colourless liquid gel.

Clinical particulars

Indications

Substitute tear fluid for the management of dry eye conditions for unstable tear film.

Dosage and method of administration

Dosage

For ocular use

Adults: one drop 3 to 4 times daily or as required, depending upon the severity of the disease.

Elderly: no dosage adjustment is necessary in the elderly (65 years or older).

Children: no specific studies have been performed in children.

Method of administration

The tube should be held vertically in order to ensure an easily detachable drop. The drop should be instilled into the conjunctival sac.

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. (See also Warning and Precautions section)
Discard four weeks after first opening.

In case of any additional local ocular treatment (e.g. glaucoma therapy) there should be an application interval of at least 5 minutes between the two medications. As Viscotears could delay the penetration of other topical ocular medications, it should always be the last medication instilled.

Contraindications

Known hypersensitivity to any of the ingredients included in Viscotears.

Special warnings and precautions for use

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.

Contact lenses should not be worn during instillation of Viscotears. Lenses should be removed before administration and should not be reinserted until at least 30 minutes have elapsed. Cetrimide, the preservative in Viscotears, may cause discoloration of soft contact lenses.

If there is no improvement after 3 days the patient should consult a physician.

Interactions

No interactions are known with Viscotears liquid gel.

Women of child-bearing potential, pregnancy, breast-feeding and fertility

Women of child-bearing potential

There is no special recommendation.

Pregnancy

No adequate animal studies have been performed with Viscotears. However, there are no concerns when the products are used as directed.

Breast-feeding

No adequate animal studies have been performed with Viscotears. It is unknown whether components of Viscotears are excreted in human milk, but there are no concerns when the product is used as directed.

Fertility

The effect of Viscotears components on fertility has not been adequately studied in animals, but there are no concerns when the products are used as directed.

Driving and using machines

Due to the high viscosity of the product, instillation of Viscotears may temporarily influence visual acuity. Patients driving vehicles or operating machines should be alerted to the possibility of temporary impairment or blurring of vision.

Adverse effects

Viscotears is generally well tolerated. The following adverse events have been reported:

Tabulated summary of adverse drug reactions from clinical trials

Adverse drug reactions to Viscotears liquid gel from clinical trials (Table 1-1) are listed by MedDRA system organ class. Within each system organ class, the adverse drug reactions are ranked by frequency, with the most frequent reactions first. Within each frequency grouping, adverse drug reactions are presented in order of decreasing seriousness. In addition, the corresponding frequency category for each adverse drug reaction is based on the following convention (CIOMS III): 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 ($< 1/10,000$).

Table 1-1 Adverse drug reactions to Viscotears liquid gel from clinical trials

Eye disorders	
Very common:	Blurred vision (transient), sticky eyelids
Common:	Eye irritation (transient)

Adverse drug reactions from spontaneous reports (frequency not known)

The following adverse drug reactions have been derived from post-marketing experience with Viscotears liquid gel via spontaneous case reports. Because these reactions are reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency which is therefore categorized as not known. Adverse drug reactions are listed according to system organ classes in MedDRA. Within each system organ class, ADRs are presented in order of decreasing seriousness.

Table 1-2 Adverse drug reactions to Viscotears liquid gel from spontaneous reports (frequency not known)

Immune system disorders
Hypersensitivity
Eye disorders
Eye pain, eye swelling, eye pruritus, eyelid oedema, ocular hyperaemia

Overdose

Not applicable.

Clinical pharmacology

Pharmacodynamics properties/Mechanism of action (MOA)

Viscotears Liquid Gel has no pharmacologically active ingredient. Viscotears Liquid Gel contains carbomer 980. After local instillation the gel 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 conventional artificial tears eye drops. The improvement in tear film stability was maintained for a period of up to 6 hours.

Data from clinical studies on healthy volunteers, patients with dry eye and patients in intensive care or during operation suggest that Viscotears Liquid Gel improves tear film stability and prolongs tear break-up time (BUT).

Pharmacokinetics

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 the carbomer (4 mio Daltons).

Clinical studies

No recent clinical trial was conducted with Viscotears.

Non-clinical safety data

All components of Viscotears are well established. Extensive use of these compounds reveals no special hazard for humans with respect to safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential and toxicity to reproduction. Repeated ocular administration in animal studies showed no untoward effects.

Pharmaceutical information

List of excipients

Cetrimide, sorbitol, sodium hydroxide, water for injection.

Incompatibilities

Cetrimide, the preservative in Viscotears, may cause discoloration of soft contact lenses (see also section 6 Warnings and precautions). Shelf life

Unopened: 3 years.

Special precautions for storage

Do not store above 25°C.

Discard 4 weeks after first opening.

Viscotears Liquid Gel must be kept out of the reach and sight of children.

Nature and contents of container

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

Special precautions for disposal

None.

Medicine Classification

General Sale Medicine

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