

Summary of Product Characteristics

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 for how to report adverse reactions.

1 NAME OF THE MEDICINAL PRODUCT

ILUBE 5% w/v Eye Drops, Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

acetylcysteine 5.0 % w/v.

Excipient(s) with known effect

Benzalkonium Chloride 0.01% w/v.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution

A clear and colourless eye drops solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

ILUBE Eye Drops are artificial tears with mucolytic and lubricant properties, suitable for the relief of dry eye syndromes associated with deficient tear secretion, impaired or abnormal mucus production.

ILUBE Eye Drops is indicated for the relief and treatment of tear deficiency and impaired mucus production.

4.2 Posology and method of administration

Posology

The usual dose is 1 or 2 drops instilled into the affected eye(s) 3 or 4 times daily.

Paediatric population

No data are available.

Method of administration

ILUBE Eye Drops are administered by topical instillation into the conjunctival sac.

4.3 Contraindications

Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Ilube Eye Drops contain benzalkonium chloride as preservative and, therefore, should not be used to treat patients who wear soft contact lenses. Discontinue use if discomfort, increased reddening or irritation occurs and persists.

4.5 Interaction with other medicinal products and other forms of interaction

Medical advice must be sought before taking Ilube Eye Drops with any medication, including medicines obtained without a prescription.

4.6 Fertility, pregnancy and lactation

This product should not be taken if the patient is pregnant, might get pregnant, or breastfeeding without seeking medical advice.

4.7 Effects on ability to drive and use machines

Patients must be advised that their vision may be blurred after using Ilube Eye Drops and must not drive or use any machines unless their vision is clear.

4.8 Undesirable effects

Patient may experience itching, redness and/ or irritation in their eye(s).

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

None known.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: Ophthalmologicals, other ophthalmologicals, ATC Code: S01X A08.

Acetylcysteine, a derivative of the naturally occurring amino acid L-cysteine, with marked mucolytic properties.

Acetylcysteine has been shown to dramatically reduce the viscosity and tenacity of sputum. The liquifying action is due to the presence of a free sulphydryl group which opens up disulphide bonds present in mucus. This pharmacological action of acetylcysteine is of benefit to patients suffering from ocular mucus abnormality.

5.2 Pharmacokinetic properties

No specific work has been carried out on the pharmacokinetic properties of acetylcysteine when used as a topical preparation for the eye. Acetylcysteine reduces the viscosity and tenacity of mucus in the eye. This, combined with the emollient properties of hypromellose, ensures lubrication and soothing relief for dry eye syndromes.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Disodium edetate
Hypromellose
Benzalkonium chloride
Sodium hydroxide
Purified water

6.2 Incompatibilities

Not Applicable.

6.3 Shelf life

2 years (unopened), 28 days (after first opening).

6.4 Special precautions for storage

Do not store above 25°C.
Keep the bottle in the outer carton in order to protect from light.
Keep the bottle tightly closed.

6.5 Nature and contents of container

A lipped Type I amber glass bottle with a push-in closure (chlorobutyl bung) containing 10 ml of solution. The bung is held in place by a polypropylene and aluminium overseal. The bung and overseal form a single integral closure (“flip-cap”). Immediately before use, the overseal and bung are removed and replaced with a polyvinyl chloride integral cap and dropper assembly, which fits over the lip of the vial. The integral cap and dropper assembly has an aperture at the end for the delivery of the product, which is closed with a small high density polyethylene screw cap.

6.6 Special precautions for disposal

Discard 28 days after first opening the pack.

7 MARKETING AUTHORISATION HOLDER

Rayner Pharmaceuticals Limited
10 Dominion Way
Worthing
West Sussex BN14 8AQ
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA2161/002/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 17 December 1992

Date of last renewal: 17 December 2007

10 DATE OF REVISION OF THE TEXT

April 2017