PACKAGE LEAFLET

Package Leaflet – Information for the User ILUBE 5% w/v eye drops, solution

Acetylcysteine

Read all of this leaflet carefully before you start using this medicine

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or your pharmacist.
- This medicine has been prescribed for you. **Do not pass it on to others.** It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

IN THIS LEAFLET

- 1. What ILUBE is and what it is used for
- 2. Before you use ILUBE
- 3. How to use ILUBE
- 4. Possible side effects
- 5. How to store ILUBE
- 6. Further information

1. WHAT ILUBE IS AND WHAT IT IS USED FOR

ILUBE is a solution that acts as an artificial tear.

It is used to provide relief for dry eyes conditions which are associated with a lack of tears or abnormal tear production. ILUBE works by reducing the stickiness of tears and lubricating dry eyes to relieve discomfort.

2. BEFORE YOU USE ILUBE

Do not use ILUBE...

• If you are allergic to acetylcysteine or any of the other ingredients listed in section 6.

Ask your doctor for advice.

Pregnancy and breast-feeding

If you are pregnant or might get pregnant, or if you are breast-feeding, talk to **your doctor** before you use ILUBE.

Driving and using machines

Your vision may be blurred after using ILUBE. Do not drive or use any machines unless your vision is clear.

Using other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Important information if you wear Contact Lenses

Do not use the drops while wearing **contact lenses**. Wait at least 15 minutes after use before putting your lenses back in. There is a preservative in ILUBE (benzalkonium chloride) that can discolour soft contact lenses.

3. HOW TO USE ILUBE

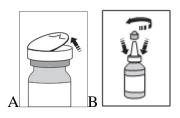
The usual dose

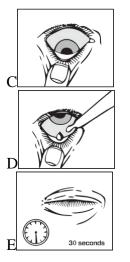
The usual dose is 1 or 2 drops into the affected eye 3 or 4 times daily or as advised by your doctor. Always use ILUBE exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

How to use

- Wash your hands before you start.
- Take the bottle, lift the side of the top as shown (see diagram A). Remove the yellow plastic disc and the adjoining aluminium ring.
- Remove the black rubber bung.
- Open the plastic bag and take out the plastic dropper.
- Push the plastic dropper onto the glass bottle. Unscrew the plastic cap as shown in diagram B.
- Tilt your head back.
- Bring the dropper close to the eye. Do this in front of a mirror if it helps.
- **Do not touch your eye or eyelid**, surrounding areas or other surfaces with the dropper. It could contaminate the drops.
- Pull down your lower eyelid with a finger (Diagram C), until there is a 'pocket' between the eyelid and your eye. Press lightly on the middle of the plastic dropper.
- Put one or two drops, as directed, in your eye (Diagram D).
- Close your eye for about 30 seconds (Diagram E).
- If you use drops in both eyes, repeat the steps for your other eye. Screw the cap on the plastic dropper.
- If a drop misses your eye, try again.
- If you forget to use ILUBE, do not worry, just use it as soon as you remember. Do not take a double dose to make up.
- If you use more ILUBE than you should, close your eyes and rinse off any excess ILUBE with warm water.
- If the contents of the bottle are swallowed, tell your doctor or the casualty department of a hospital immediately.

If you have any further questions on the use of ILUBE, ask your doctor or pharmacist.





4. **POSSIBLE SIDE EFFECTS**

Like all medicines, ILUBE can cause side effects, although not everybody gets them.

• You may experience some or all of the following effects in your eye(s): Itching, redness, irritation.

If any of the side effects get serious, or you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system:

United Kingdom

Yellow Card Scheme Website: <u>www.mhra.gov.uk/yellowcard</u>

Ireland

HPRA Pharmacovigilance Earlsfort Terrace, IRL - Dublin 2 Tel: +353 1 6764971; Fax: +353 1 6762517 Website: <u>www.hpra.ie</u> e-mail: <u>medsafety@hpra.ie</u>

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE ILUBE

- Keep out of the reach and sight of children.
- Do not store above 25°C.
- Keep the bottle tightly closed.
- Keep in the outer carton and protect from light.
- Do not use the drops after the expiry date (marked 'Exp') on the bottle and the carton. The expiry date refers to the last day of that month.
- Stop using the bottle 4 weeks after first opening, to prevent infections.
- Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.
- **Do not pass this medicine on to others**. It may harm them even if their symptoms are the same as yours.

6. FURTHER INFORMATION

What ILUBE contains

- The active substance is acetylcysteine 50 mg/ml (5 % w/v).
- The other ingredients are hypromellose, disodium edetate, benzalkonium chloride, sodium hydroxide and purified water.

What ILUBE looks like and contents of the pack

ILUBE is a clear, colourless liquid supplied in a 10 ml glass bottle. The carton also contains a white plastic dropper with a screw cap packed separately.

Marketing authorisation holder:

Moorfields Eye Hospital NHS Foundation Trust trading as Moorfields Pharmaceuticals, 25 Provost Street, London, N1 7NH, United Kingdom.

Manufacturer:

Laboratories Pharmaster, Z.I. Krafft, F-67150 Erstein, France. This leaflet was last approved in October 2015.