

Package leaflet: Information for the patient

Lumobry 0.25 mg/mL, eye drops, solution brimonidine tartrate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Lumobry eye drops medicinal product is and what it is used for
2. What you need to know before you use Lumobry
3. How to use Lumobry
4. Possible side effects
5. How to store Lumobry
6. Contents of the pack and other information

1. What Lumobry is and what it is used for

Lumobry is a drug applied on the eye(s). The product contains brimonidine tartrate as an active substance which reduces redness of the eyes by constricting the small blood vessels in the conjunctiva (the white part) of the eye.

Therapeutic indications

Lumobry, is used for short-term treatment of redness of the eye due to minor eye irritation (not caused by an infection) in adults

2. What you need to know before you use Lumobry

Do not use Lumobry:

- if you are allergic to brimonidine or any of the other ingredients of this medicine (listed in section 6).
- in children below 2 years of age.

Do not use this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before using Lumobry eye drops.

Warnings and precautions

If your doctor will be able to define the cause of your eye redness (e.g. allergic reaction, dry eye disease), appropriate measures will be introduced.

A reduction in ocular redness should occur within 5-15 minutes, however, if after the use of Lumobry eye drops the condition worsens or persists for more than 3 days (72 hours), stop using this product and seek medical attention immediately.

Stop using Lumobry and contact a doctor immediately if you develop eye irritation, eye infection, eye pain, changes in vision, continued redness, receive an eye injury, become sensitive to light.

There is a risk that brimonidine may be absorbed into the blood if you use Lumobry longer than your doctor has told you to or if you have not pressed the corner(s) of the eye near the nose after use. This may cause dizziness and sleepiness. It may also cause cardiovascular problems, especially if you have untreated cardiovascular disease, obstruction of blood vessels to the brain or the heart, Raynaud's phenomenon, low blood pressure when standing up or Buerger disease.

Children and adolescents

Lumobry should not be used in children and adolescents.

Other medicines and Lumobry

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

When Lumobry is used longer than your doctor has told you to or if you have not pressed the corner(s) of the eye near the nose after use, brimonidine may be absorbed into the blood. This can affect other medications that you may be taking. Tell your doctor if you are taking:

- medicines to treat increased pressure within the eye.
- Lumobry can reduce pressure within the eye and may increase the effect of these medicines.
- antidepressants (monoamine oxidase [MAO] inhibitors or tricyclic antidepressants)
- medications to lower your blood pressure
- alcohol, barbiturates, opiates, sedatives, or anaesthetics

Eye drops containing brimonidine can also reduce pressure within the eye. Tell your doctor or pharmacist if you are using medicines to treat ocular hypertension (increased pressure within the eye) as Lumobry may increase the effect of these medicines.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, do not use this medicine or ask your doctor or pharmacist for advice before using it.

Driving and using machines

Lumobry may affect the ability to drive and use machines. As all products administered to eye, it may cause transient blurred vision, which may impair the ability to drive or to use machinery, especially at night or in reduced lighting. If you experience such disturbances you should wait until these symptoms have cleared before driving or using machinery.

Lumobry contains benzalkonium chloride

This medicine contains 0.0034 mg benzalkonium chloride in each drop which is equivalent to 0.1 mg/mL. Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove contact lenses before using this medicine and put them back 15 minutes afterwards.

Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor.

3. How to use Lumobry

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. The drug should not be used longer than it was recommended by a doctor.

You should use the medicine onto the eye(s).

Do not apply Lumobry simultaneously with other medicinal products used in the eye. If you use other medicinal products in the eyes, you should keep the 15-minute interval between application of your medicines.

Wash your hands

Remove your contact lenses before use of the product (see section 2 Lumobry contains benzalkonium chloride).

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The cap of the bottle should be pushed down while turning then taken off.

Tilt the head back and pull down the lower eyelid gently to form a small pocket between the eyelid and the eye.

Turn the bottle up side down and squeeze until a single drop is dispensed into the eye.

Apply one drop in the affected eye(s) every 6 – 8 hours, no more than four times daily. The tip of the container should not come in contact with the eye or surrounding structures in order to prevent contamination.

After application of the Lumobry in the affected eye(s), you should press the corner(s) of the eye near the nose and close the eyelids for 2 minutes.

Put the cap back on and the bottle and close tightly straight after it has been used.

Wash your hands thoroughly after using the product.

A reduction in ocular redness should normally occur within 5-15 minutes, however, if the condition worsens or persists for more than 72 hours, you should stop using the product and your eyes should be re-evaluated by a doctor or pharmacist.

If you use more Lumobry than it is recommended

If you have taken too much Lumobry or after accidental oral ingestion, the following symptoms may occur: decreased blood pressure, weakness, vomiting, lethargy, sedation, slow or irregular heart rhythm, excessive constriction of the pupil, difficulty breathing or no breath, decreased muscle tone, decreased body temperature or seizures.

If overdose symptoms occur, talk to your doctor or go to hospital as soon as possible.

If you forget to use Lumobry

Do not take a double dose to make up for a forgotten dose.

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

4. Possible side effects

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

Common side effects (may affect up to 1 in 10 people):

- Red eyes
- Pain at the application site.

Uncommon side effects (may affect up to 1 in 100 people):

- Dry eye
- Eye sensitivity to light
- Eye discharge
- Eye irritation
- Eye pain
- Foreign body sensation in eyes
- Installation site irritation, burning or itching.
- Headache

- Palpitations
- Muscle twitching
- Lymphocytosis, monocytosis (high count of lymphocytes or monocytes in blood)
- Nasal discomfort
- Hypotension (decreased blood pressure).

Reporting of side effects

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

HPRA Pharmacovigilance

Website: <http://www.hpra.ie>

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

5. How to store Lumobry

Do not store above 25°C.

Discard 4 months after the first opening.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the box, label or bottle after 'EXP'. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Lumobry contains

The active substance is brimonidine tartrate.

The other ingredients are: Glycerol (E422), Borax (E285), Boric Acid (E284), Potassium Chloride (E508), Calcium Chloride Dihydrate, Sodium Chloride, Benzalkonium Chloride, Sodium Hydroxide (E524), Hydrochloric Acid (E507), Water for Injection.

What Lumobry looks like and contents of the pack

Lumobry is a clear, colorless to slightly yellow, sterile eye drops, solution formulated for topical delivery to the eye.

Lumobry is available in 7.5 mL fill volumes in 10 mL LDPE bottles using LLDPE dropper applicators (tips) and two-piece child-resistant PP/HDPE screw caps.

Marketing Authorisation Holder and Manufacturer

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