

Package leaflet: Information for the patient

Lumify, 0.025%, Ophthalmic Solution as Eye drops

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 **Lumify** is and what it is used for
2. What you need to know before you use **Lumify**
3. How to use **Lumify**
4. Possible side effects
5. How to store **Lumify**
6. Contents of the pack and other information

1. What Lumify is and what it is used for

Lumify eye drops is an OTC drug topically applied on the eye(s). The product contains brimonidine tartrate as an active substance. Brimonidine tartrate is an α_2 -adrenoceptors agonist (sympathomimetic) displaying potent blood-vessel constricting properties thus provides the eye blanching activity on the conjunctiva.

Therapeutic indications

Lumify, eye drops, is indicated for the topical treatment of conjunctival hyperemia (redness) due to minor eye irritation in adults and children 5 years of age and older.

2. What you need to know before you use Lumify

Do not use Lumify eye drops:

- if you are allergic to brimonidine or any of the other ingredients of this medicine (listed in section 6).
- in prolonged ocular hyperaemia (ocular redness)
- in prolonged eye irritation
- in bacterial, viral and fungal ocular infections (manifesting e.g. with the eye mucous or purulent discharge)
- in eye(s) pain
- in cases of vision changes or disturbances.

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 **Lumify** eye drops.

Warnings and precautions

Talk to your doctor, pharmacist before using **Lumify**.

For external use only.

Lumify is designed only for intermittent or occasional use.

If after the use of **Lumify** eye drops the condition worsens or persists for more than 3 days, stop using this product and refer to ophthalmologist immediately. For children 5 years of age and older, careful observation of the treatment response should be performed by parents and/or caregivers.

If after the use of **Lumify**, experience eye pain, changes in vision, skin or eye allergy, continued redness or irritation of the eye, stop using the product and refer to ophthalmologist immediately.

Eye irritation or redness caused by a serious ocular condition, such as infection, foreign body or damage to the cornea, acute glaucoma or iritis (inflammation of the iris) requires immediate medical attention.

In the case of infection at the site of application of the medicinal product, you should refer to ophthalmologist who will decide about appropriate antibacterial and/or antifungal treatment introduction. Any spread of infection requires referring to ophthalmologist who will decide about **Lumify** eye drops withdrawal till the time of infection cure.

If you suffer from cardiovascular diseases such as: severe or unstable and uncontrolled cardiovascular disease, cerebral or coronary insufficiency, Raynaud's phenomenon, orthostatic hypotension or thromboangitis obliterans (inflammation and clotting of arteries and veins of hands and feet), you should take special care when using this product since brimonidine if absorbed (when used incorrectly or for prolonged time) may affect circulatory functions and worsen disease symptoms.

If you suffer from depression, you should special attention when using this product since brimonidine, if absorbed (when used incorrectly or for prolonged time), easily passes the blood-brain barrier and attenuates the central nervous system functions. Dizziness, somnolence, sedation and other similar symptoms may occur. If you notice worsening of disease symptoms, you should refer to a doctor.

If you use contact lenses you should avoid contact them with this drug solution as it may cause lenses discolouration. After ocular installation of **Lumify** you should maintain at least 10-minute interval before lenses reinsertion.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using this medicine.

Children and adolescents

Lumify eye drops should not be used in paediatric patients younger than 5 years of age.

Other medicines and Lumify

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

No interactions are known for ocular use of brimonidine tartrate in combination with other drugs used onto the eye. However, if brimonidine is absorbed to the blood circulation after application onto the eye, it may interfere with activity of several groups of medicines administered orally or parenterally. These groups include antidepressant medicines (attenuated activity), CNS depressants (enhanced activity), hypotensive and other cardiovascular-active drugs (decreased or enhanced activity).

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Driving and using machines

Lumify 0.025%, eye drops, has minor influence on 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.

Lumify eye drops contains benzalkonium chloride

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 10 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 Lumify eye drops

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 locally onto the eye(s).

Do not apply **Lumify** eye drops simultaneously with other ophthalmic medicinal products used topically. If you use other topical ophthalmic medicinal products, you should keep the 5-minute interval between application of your medicines.

Wash your hands and remove your contact lenses before application of the product.

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

The patient's head must be tilted back, and the lower eyelid must be pulled gently down to form a small pocket between the eyelid and the eye.

The bottle should be inverted and squeezed 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 dispensing container should not contact with the eye or surrounding structures in order to prevent contamination.

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

The cap must be put back on and the bottle must be closed tightly straight after it has been used.

Wash your hands thoroughly after using the product.

Renal/hepatic impairment

Brimonidine has not been studied in patients with hepatic or renal impairment.

Use in children and adolescents

Lumify eye drops should not be used in paediatric patients younger than 5 years of age.

If you use more Lumify eye drops than it is recommended

After long-term use of **Lumify** eye drops overdose 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 Lumify eye drops

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

If you stop using Lumify eye drops

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.

In clinical studies, **Lumify** medicinal product has been shown to possess similar safety profile as the product without active substance (Placebo).

Common local adverse reactions (may occur in 1 to 10 patients per 100 treated patients):

- Ocular hyperaemia (also known as ocular redness - small dilated blood vessels)
- Installation site pain.

Uncommon local adverse reactions (may occur in 1 to 10 patients per 1000 treated patients):

- Dry eye
- Photophobia
- Eye discharge
- Eye irritation
- Eye pain
- Foreign body sensation in eyes
- Installation site irritation, burning or itching.

Uncommon systemic adverse reactions (may occur in 1 to 10 patients per 1000 treated patients):

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

5. How to store Lumify

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

Store below 30°C.

Do not use this medicine after the expiry date which is stated on the bottle label and carton. The expiry date refers to the last day of that month.

Do not use this medicine if solution changes colour or becomes cloudy.

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 Lumify contains

- **The active substance is:** Brimonidine tartrate (0.025%)
- **The other ingredients are:** glycerin, sodium borate decahydrate, boric acid, potassium chloride, calcium chloride dihydrate, sodium chloride, benzalkonium chloride, Hydrochloric acid and/or sodium hydroxide may be used to adjust pH, and water for injection.

What Lumify looks like and contents of the pack

Lumify, Brimonidine Tartrate Ophthalmic Solution, 0.025% drug product is a clear, colorless to slightly yellow, sterile, preserved ophthalmic solution formulated for topical delivery to the eye.

The multi-dose drug product is packaged in as nominal of 2.5ml or 7.5 mL fill volumes in 10 mL LDPE bottles using LLDPE tips and two-piece child-resistant closures.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Bausch & Lomb Incorporated, 400 Somerset Corporate Boulevard, Bridgewater, New Jersey 08807 United States of America

Manufacturer

Bausch & Lomb, Inc., 8500 Hidden River Parkway, Tampa, FL 33637, United States

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Council of Arab Health Ministers:

This is a Medicament

- ☐ Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- ☐ Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- ☐ The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- ☐ Do not by yourself interrupt the period of treatment prescribed for you.
- ☐ Do not repeat the same prescription without consulting your doctor.
- ☐ Keep all medicaments out of reach of children.

Council of Arab Health Ministers
Union of Arab Pharmacists