

Package leaflet: Information for the user

Lakrimont 2 mg/g EYE GEL

Carbomer 980

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

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after a few days

What is in this leaflet

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

1. What Lakrimont is and what it is used for

Lakrimont is an eye gel and each tube contains 10 grams of the medicine. It is used as a substitute for natural tears (that is, as artificial tears). It is used to treat a condition called “dry eyes” where the tears are not produced in sufficient quantities or are of poor quality. The gel protects and lubricates the surface of your eye.

2. What you need to know before you use Lakrimont

Do not use Lakrimont

- if you are allergic (hypersensitive) to carbomer or any of the other ingredients of Lakrimont (see section 6)

Warnings and Precautions

Do not inject or swallow

Wearing contact lenses is not recommended during treatment with this ophthalmic gel. If you cannot avoid wearing contact lenses, remove the lenses before using the gel, and wait at least 30 minutes before re-inserting them. You should do this because the preservative, cetrimide, can cause staining of soft contact lenses.

Replace the cap after use

If symptoms continue or worsen, the patient should be reviewed by an eye specialist

The preservative, cetrimide, can cause eye irritation

Children and adolescents aged to 18 years:

The safety and efficacy of Lakrimont in children and adolescents at the posology recommended in adults has been established by clinical experience, but no clinical trial data are available

Other medicines and Lakrimont

Please tell your doctor or pharmacist if you have any other eye disorder and are using or have recently used any other medicines for your eyes, including medicines obtained without a prescription.

In case you use any additional local ocular treatment there should be an application interval of at least 15 minutes between the two medications.

Lakrimont always should be the last medication instilled since this eye gel may prolong the ocular residence time of other eye drops

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 taking this medicine. Considering the negligible systemic penetration of carbomer after ocular administration, no effect during pregnancy or lactation is expected. Lakrimont can be used during pregnancy or lactation.

Driving and using machines

Lakrimont may temporarily blur your vision due to the viscosity of the carbomer, so do not drive or operate machinery if your vision becomes blurred immediately after you have applied the drops. Wait until your vision clears.

Lakrimont contain the preservative cetrimide , which can cause eye irritation and is known to discolour soft contact lenses. Lakrimont is not to be used while wearing contact lenses

3. How to useLakrimont

Always use Lakrimont exactly the way your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

Adults and the elderly: The usual dose is 1 drop in each eye 3 or 4 times per day or as required.

In case you use any additional local ocular treatment (e.g. glaucoma eye drops), there should be an application interval of at least 15 minutes between the two medications. Lakrimont should always be the last medication instilled.

Children and adolescents aged to 18 years:

The safety and efficacy of Lakrimont in children and adolescents at the posology recommended in adults has been established by clinical experience, but no clinical trial data are available

Instructions 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 solution

Always wash your hands before applying eye gel. Apply one drop of Lakrimont in each affected eye in the following way:

1. Remove the cap
2. Tilt your head backwards and hold the tube vertically above your eye with one hand, the dropper tip pointing downwards
3. Gently pull down your lower eye lid with the other hand
4. Look upwards and insert one small drop into the gap between the lower eye lid and the eye
5. Release the lower eyelid. Blink a few times to spread the gel evenly over your eye

6. Wipe away any excess gel from around the eyelids.

If symptoms persist or worsen, consult your eye specialist.

4. Possible side effects

Like all medicines Lakrimont can cause unwanted effects, although not everybody gets them.

Very common side effects (affects more than 1 user in 10)

Ocular effects: blurred vision (temporary), sensation of “sticky” eyelids

Common side effects (affects more than 1 in 100 people)

Ocular effects: Eye irritation (transient)

Additional adverse reactions have been reported:

Effects on the immune system: hypersensitivity

Ocular effects: eye pain, eye swelling eye pruritus, eyelid oedema, ocular hyperaemia

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

[To be completed nationally]

5. How to storeLakrimont

Keep out of the sight and reach of children

- Do not use Lakrimont after the expiry date which is stated on the tube and on the carton after (EXP). The expiry date refers to the last day of that month.
- Do not use the tube 28 days after first opening even if the tube is not empty
- Store below 25°C
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Lakrimont contains

- The active substance is carbomer 980. 1 gram eye gel contains 2mg carbomer 980.
- The other ingredients are cetrimide, sorbitol, disodium edetate, sodium hydroxide and water for injections.

What Lakrimont looks like and contents of the pack

Lakrimont is a sterile, clear and colourless eye gel in a laminated plastic tube containing 10 grams of the eye gel.

It is available in packs of 1 tube or 3 tubes. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

[To be completed nationally]

Manufacturer:

Excelvision
27 rue de la Lombardiere
07104 Annonay Cedex
France

This medicinal product is authorised in the Member States of the EEA under the following names:

Sweden, Denmark, Norway, Greece: Lakrimont

This leaflet was last revised in 2019-04-17