

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Lakrimont 2 mg/g Eye Gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One gram eye gel contains 2 mg carbomer 980.

Excipients with known effect

Cetrimide 0.1 mg/g.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye gel.

Clear and colourless gel.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Symptomatic treatment of dry eye syndrome.

4.2 Posology and method of administration

For ocular use.

Adults (including the elderly)

1 drop into the inferior conjunctival sac of the affected eye(s), 3-4 times daily or as required, depending upon symptoms resolution. No dosage adjustment is necessary in the elderly (over 65 years).

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.

Method of administration

The container must be held vertically to ensure properly sized drops. The drops should be instilled into the lower conjunctival sac by gently pulling the lower eyelid down and looking up.

The tip of the container should not come into contact with any surface, including the eye due to the risk of contamination and eye injury.

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

4.3 Contraindications

Hypersensitivity to carbomer or to any of the excipients of this product.

4.4 Special warnings and precautions for use

The wearing of contact lenses is inadvisable during treatment with this ophthalmic gel.

If wearing contact lenses is unavoidable, the lenses should be removed prior to administration of the gel, and should not be reinserted until at least 30 minutes after administering the gel. The preservative in Lakrimont, cetrimide, may cause eye irritation and may discolour soft contact lenses.

Recap the tube after use.

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

4.5 Interaction with other medicinal products and other forms of interaction

There are no known interactions with Lakrimont.

No interaction studies have been performed with Lakrimont.

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

4.6 Fertility, Pregnancy and lactation

Pregnancy

No adequate preclinical studies with Lakrimont have been conducted, however no contraindications are to be expected if the product is used as directed.

Breast-feeding

No adequate preclinical studies with Lakrimont have been conducted, however no contraindications are to be expected if the product is used as directed.

Fertility

No adequate preclinical studies with Lakrimont have been conducted, however no contraindications are to be expected if the product is used as directed.

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.

4.7 Effects on ability to drive and use machines

According to the product viscosity, Lakrimont may cause blurred vision for a few minutes after instillation, which may impair the ability to drive or to use machinery. The patient should wait until this symptom has cleared before driving or using machinery.

4.8 Undesirable effects

Eye Disorders:

Very Common ($\geq 1/10$): Blurred vision, feeling of “sticky” eyelids

Common ($\geq 1/100$ to $< 1/10$) Eye irritation (transient)

The frequency of the following adverse reactions are not known:

Immune system disorders: hypersensitivity

Eye Disorders: Eye pain, eye swelling, eye pruritus, eyelid oedema, ocular hyperaemia

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 the national reporting system: [To be completed nationally]

4.9 Overdose

No case of overdosage has been reported with eye gels of 0.2% carbomer 980.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Ophthalmologicals, artificial tears. ATC-code: S01XA20

Lakrimont is a liquid gel containing carbomer 980, a high molecular weight polymer. The gel spreads rapidly over the ocular surface and forms a transparent film which lubricates and temporarily supplements the insufficient tear fluid.

5.2 Pharmacokinetic properties

The retention time of the gel on the ocular surface is about 15 minutes. Corneal penetration is unlikely due to the high molecular weight of carbomer (4 mio D).

5.3 Preclinical safety data

Preclinical data based on studies of local tolerance after repeated administration reveal no special risk (see section 4.6)

Non-clinical data reveal no special hazard for humans based on the available studies of safety pharmacology, acute and chronic toxicity, genotoxicity, carcinogenic potential and toxicity to reproduction.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cetrimide

Disodium edetate

Sorbitol

Sodium hydroxide (for pH adjustment)

Water for injections.

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf life

Before first opening: 3 years.

After first opening: Use within 28 days.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

Polyfoil laminate tube with a HDPE cannula and HDPE closure containing 10g gel.

Packs of 1x 10g or 3 x 10 g.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

[To be completed nationally]

8 MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

[To be completed nationally]

10 DATE OF REVISION OF THE TEXT

2019-04-17