LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Lakrimont
(carbomer)

SE/H/1517/01/E/02

Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.lakemedelsverket.se E-mail: registrator@mpa.se

Summary Public Assessment Report

Lakrimont

(carbomer)

Eye gel, 2 mg/g

This is a summary of the public assessment report (PAR) for Lakrimont. It explains how Lakrimont was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Lakrimont.

For practical information about using Lakrimont, patients should read the package leaflet or contact their doctor or pharmacist.

What is Lakrimont and what is it used for?

Lakrimont is a 'hybrid medicine'. This means that it is similar (*therapeutically equivalent*) to a reference medicine containing the same active substance.

The reference medicine for Lakrimont is Civigel 2 mg/g eye gel.

Lakrimont is used to treat a condition called "dry eyes".

How does Lakrimont work?

Lakrimont is used as a substitute for natural tears (that is, as artificial tears). The gel protects and lubricates the surface of the eye which helps if tears are not produced in sufficient quantities or are of poor quality.

How is Lakrimont used?

The pharmaceutical form of Lakrimont is eye gel for administration in the eyes.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can be obtained without a prescription.

What benefits of Lakrimont have been shown in studies?

Because Lakrimont is a hybrid application and is considered to be therapeutically equivalent, to the reference product Civigel, their benefits and risks are taken as being the same as those of the reference medicine.

What are the possible side effects of Lakrimont?

For the full list of all side effects reported with Lakrimont, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Lakrimont approved?

This medicine is similar to a reference medicine containing the same active substance. No new or unexpected safety concerns arose from the application. Therefore, the Medical Products Agency in Sweden decided that the benefit of Lakrimont are greater than its risks and recommended that it be approved for use.

What measures are being taken to ensure the safe and effective use of Lakrimont?

A risk management plan has been developed to ensure that Lakrimont is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Lakrimont, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Lakrimont

The marketing authorisation for Lakrimont was granted on 2011-05-13 in Sweden.

The full PAR for Lakrimont can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Lakrimont, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2019-05-09.