Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Liposic 2 mg/g eye gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 g of eye gel contains 2mg of carbomer.

For a full the list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye gel
White, turbid, highly viscous, gel.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Symptomatic treatment of dry eye syndrome.

4.2 Posology and method of administration

Posology
Therapy of dry eye conditions requires an individual dosage regimen.
According to the severity and intensity of the symptoms, instill one drop into the conjunctival sac 3-5 times daily; and approximately 30 minutes before going to bed (otherwise there is a risk of sticky eyelids).

Children and adolescents aged to 18 years
The safety and efficacy ofLiposic ® 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
Ocular use.
Generally, an ophthalmologist should be consulted when treating keratoconjunctivitis sicca, which normally turns out to be long-term or permanent therapy.

An appropriate drop size is obtained when the tube is held in a vertical position above the eye during instillation.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Contact lenses should be removed prior to administration, and may be inserted again 30 minutes after Liposic2 mg/g Eye gel has been instilled. Liposic 2 mg/g Eye gel may prolong the contact-time of topically applied drugs in ophthalmology.
Concomitant ocular medication should be administered 15 minutes prior to instillation of Liposic 2 mg/g Eye gel (see section 4.5).

If the symptoms of the dry eye continue or worsen, treatment should be stopped and an ophthalmologist should be consulted.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

No studies have been performed.

Pregnancy:
There are no data from the use of carbomer in pregnant women.
Animal studies do not indicate direct to reproductive toxicity (see section 5.3).
As a precautionary measure it is preferable to avoid the use of Liposic 2 mg/g Eye gel during pregnancy.

Breastfeeding
It is unknown whether Carbomer/metabolite are excreted in human milk.
A risk to the newborns/infants cannot be excluded.
A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from Liposic 2 mg/g Eye gel therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.

Fertility
No studies have been performed.

4.7 Effects on ability to drive and use machines

Liposic 2 mg/g Eye gel has a moderate influence on the the ability to drive and use machines.
When used as indicated, this medicinal product may impair visual acuity for about five minutes due to the formation of streaks after gel application, and patients should exercise caution when driving vehicles or operating machinery.

4.8 Undesirable effects

Adverse reactions have been ranked under headings of frequency using the following convention:
very common (≥1/10);
common (≥1/100 to < 1/10)
uncommon (≥ 1/1.000 to < 1/100)
rare (≥ 1/10.000 to < 1/1.000)
very rare (< 1/10.000)
not known (cannot be estimated from the available data)

Eye disorders very rare (< 1/10.000)	burning eyes eye redness eyelid eczema foreign body sensation in eyes giant papillary conjunctivitis itching eyes, sticky eye sensation superficial punctate keratitis tearful eyes vision blurred

These reactions could have either occurred due to the preservative contained (cetrimide) or as intolerance reactions to one of the other ingredients.
Blurred vision can occur after instillation of Liposic ® due to the high viscosity of the preparation. In clinical studies with Liposic ® only one non-serious topical ocular adverse reaction was recorded as a single observation (burning eyes).

Paediatric population
No special information have been reported.

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:
Ireland
HPRA Pharmacovigilance
Earlsfort Terrace; IRL - Dublin 2
Tel: +353 1 6764971; Fax: +353 1 6762517
Website: www.hpra.ie; e-mail: medsafety@hpra.ie

4.9 Overdose

No case of overdose has been reported.

Paediatric population
No special information have been reported for the paediatric population.

5 PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Artificial tears
ATC code S01XA20

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: artificial tears and other indifferent preparations
ATC code S01XA20
Liposic, 2 mg/g, eye Eye gel is based on a high molecular weight hydrophilic polymer. Its pH and osmolality are similar to those of the normal tear film. Due to its physical properties, the eye gel binds water and forms a translucent lubricating and wetting film on the surface of the eye. The gel structure is destroyed by the salts contained in the lacrimal fluid and releases moisture. A study in 54 patients with keratoconjunctivitis sicca found that Liposic 2 mg/g Eye gel therapy prolonged tear break-up time from a mean of 5.3 seconds to 11.2 seconds after 6 weeks. Schirmer I-test values were increased from a mean of 4.8 mm to 10.7 mm after 6 weeks.

5.2 Pharmacokinetic properties

No controlled animal nor human pharmacokinetic studies with this product are available. However, absorption or accumulation in eye tissues can presumably be excluded due to the high molecular weight of carbomer. Clinical studies performed with an essentially similar product have shown that ocular residence time can be assumed to be approximately up to 90 minutes.

Paediatric population
No data available.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cetrimide, preservative
Sorbitol
Medium-chain triglycerides
Sodium hydroxide (for pH adjustment)
Water for Injection

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

28 days after opening of the container.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Tubes of 5 g eye gel. Packs with one or three tubes of 5 g eye gel.
Tubes of 10 g eye gel. Packs with one or three tubes of 10 g eye gel.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Bausch + Lomb Ireland Limited
3013 Lake Drive
Citywest Business Campus
Dublin 24
D24 PPT3
Ireland

8 MARKETING AUTHORISATION NUMBER

PA23259/009/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 22 March 2002

Date of last renewal: 20 March 2007

10 DATE OF REVISION OF THE TEXT

July 2022