# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

LACRI-LUBE Eye Ointment

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

There is no specific active ingredient.

Excipients: 1g of LACRI-LUBE contains 2mg wool alcohols
For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Eye ointment
Smooth, homogenous, off white, sterile ophthalmic ointment.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

As a lubricant and for protection in dry eye.

### 4.2 Posology and method of administration

A small amount of ointment as needed or directed by the physician into the topical instillation into the conjunctival sac.

### 4.3 Contraindications

Use in patients hypersensitive to lanolin alcohols or to any of the excipients.

### 4.4 Special warnings and precautions for use

If irritation, pain, redness and changes in vision occur or worsen, treatment discontinuation should be considered and a re-evaluation of the patient’s condition should be made.

Wool alcohols may cause local skin reactions (e.g. Contact dermatitis)

Contact lenses should not be worn during instillation of the drug. After instillation there should be an interval of at least 30 minutes before reinsertion.

In circumstances where concomitant topical ocular medication is necessary, there should be an interval of at least 5 minutes between the two medications. LACRI-LUBE should always be the last medication instilled.

To avoid injury to the eye, do not allow the tube tip to come into contact with the eye
during application of the product.

### 4.5 Interaction with other medicinal products and other forms of interaction

No interactions have been observed with LACRI-LUBE. Since the constituents have a well established medicinal use, no interactions are anticipated.

## 4.6 Fertility, pregnancy and lactation

*Pregnancy:*
No effects during pregnancy are anticipated since there is no systemic exposure of the pregnant woman to a pharmacologically active substance.

*Breastfeeding:*
No effects on the breastfed infant are anticipated since there is no systemic exposure of the breast-feeding woman to a pharmacologically active substance.

*Fertility:*
There are no known fertility implications with the use of LACRI-LUBE.

## 4.7 Effects on ability to drive and use machines

May cause transient blurring of vision. Do not drive or use machinery unless vision is clear.

## 4.8 Undesirable effects

No adverse events have been reported in clinical trials. All adverse events recorded below were identified in post-marketing reports.

The frequency of adverse reactions documented from spontaneous post-marketing reporting is given below and is defined as follows: Not Known (cannot be estimated from available data).

Within each frequency grouping, the undesirable effects are presented in order of decreasing seriousness:

*Eye Disorders:*
Not known: Eye pain (including stinging), eye irritation (including burning sensation), eye allergy, vision blurred, eye swelling, eye inflammation, eyelid oedema, eye pruritus, eye discharge, foreign body sensation, ocular/conjunctival hyperaemia, eyelid erythema, lacrimation increased.

*Immune System disorders:*
Not known: Hypersensitivity

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:

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

Accidental topical ocular overdosage will present no hazard, apart from a potential transient blurring effect on vision (see section 4.7).

# 5 PHARMACOLOGICAL PROPERTIES

## 5.1 Pharmacodynamic properties

Pharmacotherapeutic group (ATC code) = *S01X A20*.

The ingredients of LACRI-LUBE are pharmacologically inert, bland oleaginous substances for lubrication and to maintain hydration of the ocular surfaces by occlusion.

## 5.2 Pharmacokinetic properties

Not applicable.

## 5.3 Preclinical safety data

Not applicable.

# 6 PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

White soft paraffin (white petroleum jelly)
Liquid paraffin
Wool alcohols

## 6.2 Incompatibilities

Not applicable

## 6.3 Shelf life

Unopened: 3 years.
Opened: 1 month (28 days).

## 6.4 Special precautions for storage

Do not store above 25°C.

## 6.5 Nature and contents of container

An aluminium tube with an ophthalmic delivery tip, an inner coating of protective lacquer and a polyethylene cap, containing 3.5g or 5g of sterile ophthalmic ointment.

Not all pack sizes may be marketed.

## 6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

## 7 MARKETING AUTHORISATION HOLDER

Allergan Pharmaceuticals Ireland
Castlebar Road
Westport
Co. Mayo

## 8 MARKETING AUTHORISATION NUMBER

PA 148/38/1

## 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25 January 1984

Date of last renewal: 25 January 2009

## 10 DATE OF REVISION OF THE TEXT

December 2014