

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Liquifilm Tears Ocular Lubricant, 1.4% w/v, eye drops, solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Polyvinyl alcohol 1.4% w/v

Excipient: Benzalkonium Chloride 0.005% w/v

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution.

A clear, colourless solution with a pH of 6.0-7.5 and osmolality of 200-260 mOsm/kg.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As a lubricant and artificial tear in dry eye and other ocular irritation syndromes.

4.2 Posology and method of administration

Dosage schedule: One to two drops as required or directed.

Route of administration: Topical instillation into conjunctival sac.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients.

Use with soft contact lenses.

4.4 Special warnings and precautions for use

If irritation, pain, redness and changes in vision occur or worsen or persist for more than 72 hours, treatment should be discontinued and a new assessment considered.

To avoid contamination, the dropper tip should not be allowed to touch the eye or any other surface.

Contact lenses should be removed before each application and may be reinserted after 15 minutes.

Liquifilm Tears contain benzalkonium chloride which is irritant to the eye and could cause discolouration of soft lenses. Avoid contact with soft contact lenses. Remove contact lenses before Liquifilm Tears is used and wait for at least 15 minutes before reinsertion.

Concomitant ocular medication should be administered 15 minutes prior to the instillation of Liquifilm Tears.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

The constituents of Liquifilm Tears have been used as pharmaceutical agents for many years with no untoward effects. No special precautions are necessary for the use of Liquifilm Tears in pregnancy and lactation.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.

Based upon the information available, Liquifilm Tears has no or negligible influence on the ability to drive and use machines. However, it may cause transient blurring of vision. Do not drive or use hazardous machinery unless vision is clear.

4.8 Undesirable effects

The following undesirable effects have been reported since Liquifilm Tears was marketed.

Frequency:

Not known: the incidence cannot be determined from available information.

Eye disorders:

Not known: Eye irritation, eye pain, ocular hyperaemia, lacrimation increased, foreign body sensation, eye pruritus.

Immune system disorders:

Not known: hypersensitivity

4.9 Overdose

No case of overdose has been reported.

Accidental overdosage will not present any hazard.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Artificial tears and other indifferent preparations, ATC code: S01AX20

Liquifilm Tears exerts a mechanical, not a pharmacological action. The viscosity and lubricating enhancing agent is polyvinyl alcohol.

Liquifilm Tears lowers the surface tension at the surface of the corneal epithelium, providing a lubricant layer that enhances patient comfort. Liquifilm Tears can help to restore normal tear film tonicity and to act as a wetting agent for lipid-, aqueous- and mucin-deficient eyes.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

The constituents of Liquifilm Tears have been used safely in pharmaceutical products for many years. Topical administration in animal studies showed no untoward effects.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride
Sodium phosphate dibasic
Sodium phosphate monobasic
Benzalkonium chloride
Disodium edetate
Hydrochloric acid or sodium hydroxide (for pH adjustment)
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years in the unopened container.
Discard any unused contents 28 days after opening the bottle.

6.4 Special precautions for storage

Do not store above 25°C.
Do not refrigerate or freeze.

6.5 Nature and contents of container

Low density polyethylene (LDPE) bottle and tip and medium impact polystyrene (MIPS) screw cap. Safety seal to ensure integrity of the container.

Liquifilm Tears is available in 15 ml bottles.

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
County Mayo

8 MARKETING AUTHORISATION NUMBER

PA 148/26/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st November 1982

Date of last renewal: 4th July 2008

10 DATE OF REVISION OF THE TEXT

January 2009