SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

LIQUIVISC™ 2.5 mg/g, eye gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Carbomer 974P 2.5 mg/g.

Excipient with known effect: benzalkonium chloride (0.06 mg/g).

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye gel
Slightly yellow and opalescent gel.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Symptomatic treatment of dry eye syndrome.

4.2 Posology and method of administration

Ocular use.

Adults (including the elderly):

Instil one drop of the gel into the inferior conjunctival cul-de-sac 1 to 4 times daily according to the degree of ocular trouble.

Children and adolescents aged to 18 years:

The safety and efficacy of LIQUIVISC 2.5 mg/g eye gel in children and adolescents at the posology recommended in adults has been established by clinical experience, but no clinical trial data are available.

After instillation, the bottle should be stored vertically with the dropper downwards to facilitate the formation of drops when next used.

Do not touch the eye with the dropper tip. Replace the cap after use.

4.3 Contraindications

Hypersensitivity to any of the components of the product.

4.4 Special warnings and precautions for use

This medicine contains 0.0015 mg benzalkonium chloride in each drop.

Benzalkonium chloride is commonly used as a preservative in ophthalmic products and has been reported rarely to cause punctate keratopathy and/or ulcerative keratopathy.

Benzalkonium chloride has also been reported to cause eye irritation, symptoms of dry eyes and may affect the tear film and corneal surface. Should be used with caution in dry eye patients and in patients where the cornea may be compromised.
Patients should be monitored in case of prolonged use.

Contact lenses:
Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. Patients should be advised to remove contact lenses before using this medicinal product and to wait at least 30 minutes before reinsertion.

4.5 Interaction with other medicinal products and other forms of interaction

In case of concomitant use with other eye drops, wait for 15 minutes between instillations.
LIQUIVISC™ 2.5 mg/g, eye gel should be the last medication instilled.

4.6 Pregnancy and lactation

LIQUIVISC™ 2.5 mg/g, eye gel was not studied in pregnant and breast-feeding women.
Caution should be exercised when prescribing to pregnant or breast-feeding women.

4.7 Effects on ability to drive and use machines

Vision may be blurred for a few minutes after the instillation.
If affected, the patient should be advised not to drive or operate hazardous machinery until normal vision is restored.

4.8 Undesirable effects

As for other eye drops, possibility of mild transient stinging or burning upon instillation.

Blurred vision may occur briefly after instillation until the gel is evenly distributed over the eye surface.

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 Yellow Card Scheme.
Website: www.mhra.gov.uk/yellowcard

4.9 Overdose

Any ocular overdose or oral intake that could occur is of no clinical relevance.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

TEAR SUBSTITUTE
(S : Sensory organ (eye))

- Fluid eye gel based on a high molecular weight hydrophilic polymer (carbomer 974P).
- Due to its physical properties, this gel forms a transparent lubricating and wetting film on the surface of the eye, temporarily compensating for tear insufficiency.
- Its pH (7.3) and osmolality are similar to those of the normal tear film.
- Its viscosity (700mPas) is greater than that of artificial tears, allowing less frequent administration.

5.2 Pharmacokinetic properties

Because of the relatively large size of the carbomer molecule, penetration through the cornea is unlikely.

The persistence time of the gel on the eye surface is about 30 minutes.

5.3 Preclinical safety data

Data from subacute toxicity and local tolerance studies do not show any relevant findings.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium chloride, sorbitol, lysine monohydrate, sodium acetate trihydrate, polyvinyl alcohol, water for injections.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

Shelf life prior to opening
30 months

In-use shelf life
4 weeks

6.4 Special precautions for storage

Do not store above 25°C. Store container in the outer carton, in order to protect from light.

6.5 Nature and contents of container

10g in 10ml bottle (PE) with dropper (PE).

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

LABORATOIRES THEA
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8 MARKETING AUTHORISATION NUMBER(S)

PL 20162/0009

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10/06/2008

10 DATE OF REVISION OF THE TEXT

04/03/2021