Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Artelac 3.2 mg/ml Eye Drops, Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of solution contains 3.2 mg hypromellose equivalent to hypromellose 0.32 % w/v.
Excipients with known effect
Disodium phosphate dodecahydrate and Sodium dihydrogen phosphate dihydrate (0.051 mg phosphates in each drop which is equivalent to 1.84 mg/ml)

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution.
Sterile solution for eye drops.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

This medicinal product acts as a lubricant and artificial tear in the symptomatic treatment of dehydration of the cornea and conjunctiva.

4.2 Posology and method of administration

Posology
Suitable for use in adults and children.
Unless otherwise directed, instill 1 drop into the conjunctival sac (corner of the eye nearest the nose) 3-5 times per day or as required, to provide sufficient lubrication.

Method of administration

For ocular use.
Therapy of dry eye syndrome requires an individual dosage regimen.

4.3 Contraindications

There are no known contra-indications except use in patients hypersensitive to theactive substance (hypromellose) or to any of the excipients.

4.4 Special warnings and precautions for use

If irritation persists or worsens or new eye signs or symptoms develop, discontinue use and consult a doctor. Wearers of soft contact lenses should remove their lenses before Artelac is administered and should wait for at least 15 minutes before they insert them again.

Ensure the dropper tip does not touch any surface including the eye surface. Wearers of soft contact lenses should remove their lenses before Artelac 3.2mg/ml Eye drops solution is administered and should wait for at least 15 minutes before they insert them again.

Ensure the dropper tip does not touch any surface including the eye surface.

4.5 Interaction with other medicinal products and other forms of interaction

None.

4.6 Fertility, pregnancy and lactation

Pregnancy

Artelac 3.2mg/ml Eye Drops Solution can be used in pregnancy.

Breast-feeding

Artelac 3.2mg/ml Eye Drops Solution can be used during lactation.

Fertility

Artelac 3.2mg/ml Eye Drops Solution is not expected to have any effect on fertility.

4.7 Effects on ability to drive and use machines

Artelac 3.2mg/ml Eye Drops Solution on instillation may cause a short term blurring of vision when first used. If affected wait until vision has cleared before driving or operating machinery.

4.8 Undesirable effects

The following adverse reactions have been reported following administration of Artelac 3.2 mg/ml Eye Drops Solution.

Eye disorder:

Very rare (<1/10,000):
Cases of corneal calcification have been reported very rarely in association with the use of phosphate containing eye drops in some patients with significantly damaged corneas.

Not known: Brief blurred vision or a slight stinging sensation on instilling Artelac.

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

None.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group:
Ophthalmologicals: other ophthalmologicals
ATC code: S01X A20
Methylhydroxypropylcellulose prolongs adhesion, enhances moistening of the cornea and conjunctiva and allows for a smoother movement of the conjunctiva over the cornea.

5.2 Pharmacokinetic properties

Methylhydroxypropylcellulose does not permeate the cornea or reach the systemic circulation via the ophthalmic vessels.

5.3 Preclinical safety data

Methylhydroxypropylcellulose has proved to be very well tolerated in local toxicity studies.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cetrimide
Disodium phosphate dodecahydra
Sodium dihydrogen phosphate dihydrate
Disodium edetate
Sorbitol (E420)
Water for injections

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.
Discard within 28 days of first opening.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

10 ml round transparent white bottle (LDPE) with white dropper plug (LDPE) and white cap (HDPE).

6.6 Special precautions for disposal

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

PA23259/004/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 09 July 1996

Date of last renewal: 09 July 2006

10 DATE OF REVISION OF THE TEXT

October 2023