

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Artelac Preservative Free Single Dose Unit

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 (0.068 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 in single-dose container. (Eye Drops, Solution)

Sterile solution for eye drops, presented in plastic single-dose, single-use units.

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.

Artelac Preservative Free Single Dose Unit is indicated in adults and children.

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 to 5 times per day or as required, to provide sufficient lubrication.

Leave an interval of at least 5 minutes before instilling another ophthalmic medication.

Method of administration

For ocular use only.

Therapy of dry eye syndrome requires an individual dosage regime.

4.3 Contraindications

There are no known contra-indications except use in patients hypersensitive to the active substance (hypromellose) or to any of the excipients listed in section 6.1.

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 Preservative Free Single Dose Unit 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 interactions

None

4.6 Fertility, pregnancy and lactation

Pregnancy

Artelac Preservative Free Single Dose Unit can be used in pregnancy.

Breast-feeding

Artelac Preservative Free Single Dose Unit can be used in lactation.

Fertility

Artelac Preservative Free Single Dose Unit is not expected to have any effect on fertility.

4.7 Effects on ability to drive and use machines

Artelac Preservative Free Single Dose Unit 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 Preservative Free Single Dose Unit.

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 Preservative Free Single Dose Unit.

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 HPRC 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

Disodium phosphate dodecahydrate
Sodium dihydrogen phosphate dihydrate
Sorbitol (E420)
Water for injections

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Shelf-life as packaged for sale: 2 years.
Shelf-life after first opening the container: For single-use only.
Discard immediately after use.

6.4 Special precautions for storage

Do not store above 25°C. Keep container in the outer carton.

6.5 Nature and contents of container

0.6 ml single-dose unit, composed of LDPE packaged in 30, 60 and 120 unit pack sizes.

6.6 Special precautions for disposal

Avoid contamination during use. Artelac Preservative Free Single Dose Unit eye drops are sterile until first opened. For single use only. Each carton contains a patient insert with instructions for use.

7 MARKETING AUTHORISATION HOLDER

Bausch + Lomb Ireland Limited
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Dublin 24
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8 MARKETING AUTHORISATION NUMBER

PA23259/004/002

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

March 2022