

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 3.2mg hypromellose (0.32% w/v).
For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution in single dose container. (Eye Drops, Solution)

Product imported from France:

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

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

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

Dosage

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.

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 ingredients of the preparation.

4.4 Special warnings and precautions for use

If irritation persists, discontinue use and consult a doctor.

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

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

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

Brief blurred vision or a slight stinging sensation on instilling Artelac Preservative Free Single Dose Unit.

4.9 Overdose

None.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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

The shelf life expiry date of this product shall be the date shown on the single dose containers and outer carton of the product as marked in the country of origin.

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

Cardboard outer containing 60 x 0.5ml single dose units.

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

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 PARALLEL PRODUCT AUTHORISATION HOLDER

Imbat Limited
Unit L2, North Ring Business Park
Santry
Dublin 9
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/207/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 4th July 2014

10 DATE OF REVISION OF THE TEXT