

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Artelac Preservative Free Single Dose Unit 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 (0.068 mg phosphates in each drop which is equivalent to 1.84 mg/ml)

For the 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

As per PA23259/004/002

5 PHARMACOLOGICAL PROPERTIES

As per PA23259/004/002

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 container and outer package of the product on the market 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

0.5 ml single-dose unit, composed of polyethylene packaged in 30 or 60 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 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing Ltd.
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/454/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Last updated: April 2020

10 DATE OF REVISION OF THE TEXT

January 2023