

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.

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

Sorbitol
sodium dihydrogen phosphate dihydrate
disodium phosphate dodecahydrate
water for injections

6.2 Incompatibilities

Not applicable

6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on the bottle and outer package of the product on the market in the country of origin.

Shelf life after first opening the container: single use only.
Discard immediately after use.

6.4 Special precautions for storage

Do not store above 25°C.
Keep the single-dose units in the outer box.

6.5 Nature and contents of container

0.5 ml single-dose unit, packaged 60 unit pack sizes.

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

Lexon Pharmaceuticals (Ireland) Limited
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Harcourt Centre
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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA23176/023/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 31st January 2014

10 DATE OF REVISION OF THE TEXT

July 2022