

# 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

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 LDPE packaged in 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**

IMED Healthcare Ltd.  
Unit 625 Kilshane Avenue  
Northwest Business Park  
Ballycoolin  
Dublin 15  
Ireland

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1463/099/001

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 17th October 2014

## **10 DATE OF REVISION OF THE TEXT**

April 2022