Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Celluvisc 1% w/v Eye drops, solution, unit dose

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains 10 mg carmellose sodium.

One drop (»0.05ml) contains 0.5 mg of carmellose sodium.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution

Product imported from France and Portugal:
A clear, colourless to slightly yellow viscous solution

4 CLINICAL PARTICULARS

As per PA1824/016/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1824/016/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride
Sodium lactate
Potassium chloride
Calcium chloride
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product is the date shown on each, single dose container and outer carton of the product as marketed in the country of origin.
The eye drop solution should be used immediately after opening. Any unused solution should be discarded.

6.4 Special precautions for storage

Do not store above 25°C
Keep the single dose containers in the pouch and place the pouch back in the outer carton.
Pouch is required to prevent moisture loss.

6.5 Nature and contents of container

Clear, single-dose containers formed with a twist-off tab in an over labelled outer container.
Each unit is filled with 0.4ml of solution.
Pack sizes: 60 single-dose containers
Each foil pouch contains 10 single-dose containers

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

Ensure that the single dose container is intact before use. Discard any unused solution (ie once opened do not re-use container for subsequent doses)

7 PARALLEL PRODUCT AUTHORISATION HOLDER

IMED Healthcare Ltd.
Unit 625 Kilshane Avenue
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Ballycoolin
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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/147/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28th August 2009

10 DATE OF REVISION OF THE TEXT

June 2025