Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Celluvisc 1.0% w/v eye drops, solution, unit dose

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains 10 mg carmellose sodium.

One drop (≈0.05 ml) 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;
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 shall be the date shown on the container and outer package of the product on the market 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 back in the outer carton. Pouch is required to prevent moisture loss.

6.5 Nature and contents of container

Clear, single-dose containers made from low density polyethylene formed with a twist-off tab.
Each unit is filled with 0.4 ml of solution.
Pack sizes: 30 or 60 foil pouched single-dose containers. Each foil pouch contains 10 single-dose containers.
Not all pack size may be marketed.

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 (i.e. once opened do not re-use container for subsequent doses).

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/259/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 15th April 2011

10 DATE OF REVISION OF THE TEXT

November 2025