

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 (\approx 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 PA0148/059/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0148/059/001

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 for 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.
Store in the original pack to protect from light.

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. Strips of 5 containers
Pack size 30 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 (i.e. once opened do not re-use container for subsequent doses).

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA23176/016/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 17th June 2011

10 DATE OF REVISION OF THE TEXT

February 2022