

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Monopost Unidose 50 micrograms/ml eye drops, solution in single-dose container

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml eye drops solution contains 50 micrograms of latanoprost.

One drop contains approximately 1.5 micrograms of latanoprost.

Excipient with known effect: contains polyethylene glycol glycerol hydroxystearate 40

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution in single-dose container.

Product imported from Greece;

The solution is a slightly yellow and opalescent solution.

4 CLINICAL PARTICULARS

As per PA1107/007/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1107/007/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polyethylene glycol glycerol hydroxystearate 40

Sorbitol

Carbomer 974P

Polyethylene glycol 4000

Ethylenediaminetetraacetate disodium salt

Sodium hydroxide (for pH adjustment)

Water for injections

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product is the date shown on the container and outer package of the product on the market in the country of origin.

After first opening of the sachet:

For sachet of 5 single-dose containers: use the single-dose containers within 7 days

For sachet of 10 single-dose containers: use the single-dose containers within 10 days

After first opening of the single-dose container: use immediately and discard the single-dose container after use.

6.4 Special precautions for storage

Store below 25 °C.

For storage after first opening of the medicinal product, see section 6.3.

6.5 Nature and contents of container

5 or 10 single-dose containers containing 0.2 ml of eye drops solution are packed in sachet. Pack size: 30 single-dose containers.

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/449/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 31st May 2019

10 DATE OF REVISION OF THE TEXT

October 2020