

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

Macrogolglycerol 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.

pH: 6.5 – 7.5

Osmolality: 250-310 mosmol/kg

4 CLINICAL PARTICULARS

As per PA1107/007/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1107/007/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Macrogolglycerol hydroxystearate 40

Sorbitol

Carbomer 974P

Macrogol 4000

Disodium edetate

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: 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.

6.5 Nature and contents of container

10 single-dose containers containing 0.2 ml of eye drops solution packed in a sachet.

Each pack contains 30 single-dose containers.

6.6 Special precautions for disposal and other handling

No special requirements

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Lexon (UK) Limited
Unit 18, Oxleasow Road
East Moons Moat
Redditch
Worcestershire
B98 0RE
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1097/071/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10th July 2020

10 DATE OF REVISION OF THE TEXT

February 2021