Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Xalatan 50 micrograms/mL eye drops, solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 mL eye drops solution contains 50 micrograms of latanoprost.

One drop contains approximately 1.5 micrograms latanoprost.

Excipient(s) with known effect:
Benzalkonium chloride
Sodium dihydrogen phosphate monohydrate
Anhydrous Disodium phosphate
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution.

Product sourced from Italy, France, The Netherlands, Norway and the United Kingdom.
The solution is a clear colourless liquid.

4 CLINICAL PARTICULARS

As per PA0822/140/001.

5 PHARMACOLOGICAL PROPERTIES

As per PA0822/140/001.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride
Benzalkonium chloride
Sodium dihydrogen phosphate monohydrate (E339a)
Anhydrous disodium phosphate (E339b)
Water for injections

6.2 Incompatibilities

In vitro studies have shown that precipitation occurs when eye drops containing thiomersal are mixed with Xalatan. If such medicinal products are used, the eye drops should be administered with an interval of at least five minutes.

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.

After first opening of container: 4 weeks

6.4 Special precautions for storage

Keep the bottle in the outer carton in order to protect from light.
Do not store above 25°C.

6.5 Nature and contents of container

Dropper container (5ml) with either a screw cap and tamper evident overcap or with a screw cap and tamper-evident ring.
Each dropper container contains 2.5 mL eye drops solution corresponding to approximately 80 drops of solution.
Pack sizes: 1 x 2.5 mL.

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/267/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 8th April 2011

10 DATE OF REVISION OF THE TEXT

December 2020