

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Xalatan 50 micrograms/ml eye drops, solution.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

100 ml eye drops solution contains 5mg latanoprost.

One drop contains approximately 1.5 micrograms latanoprost.

Excipient: Benzalkonium chloride 0.02% w/v is included as a preservative.

For a 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
Anhydrous disodium phosphate
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 drugs are used, the eye drops should be administered with an interval of at least five minutes.

6.3 Shelf life

Before first opening: 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 container: 28 days (4 weeks)

6.4 Special precautions for storage

Product imported from France: Store in a refrigerator (2°C – 8°C). Keep the bottle in the outer carton in order to protect from light. After first opening the bottle: do not store above 25°C and use within four weeks.

Product imported from Italy, The Netherlands, Norway and the United Kingdom: Keep the bottle in the outer carton in order to protect from light. Do not store above 25°C and use within four weeks after first opening the bottle.

6.5 Nature and contents of container

Dropper container (5 ml) 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 size: 1 x 2.5 ml

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

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

July 2016