

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.

Excipients with known effect:

Benzalkonium chloride 0.2 mg/mL is included as a preservative.

Sodium dihydrogen phosphate monohydrate.

Disodium phosphate anhydrous.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution.

Product imported from Lithuania:

The solution is a clear, colourless liquid.

4 CLINICAL PARTICULARS

As per PA23055/009/001

5 PHARMACOLOGICAL PROPERTIES

As per PA23055/009/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride

Benzalkonium chloride

Sodium dihydrogen phosphate monohydrate

Disodium phosphate anhydrous

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 is the date shown on the container and outer carton of the product as marketed in the country of origin.

After first opening of container: 4 weeks.

6.4 Special precautions for storage

Do not store above 25°C

After first opening: Use within 4 weeks (see section 6.3 of SmPC PA23055/009/001).

Keep the bottle in the outer carton in order to protect from light.

6.5 Nature and contents of container

Dropper container (5 mL) of polyethylene with a screw cap and tamper evident overcap of polyethylene.

Each dropper container contains 2.5 mL Eye drops.

Pack sizes: 1 x 2.5 mL.

6.6 Special precautions for disposal

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

PPA0465/520/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14th November 2025

10 DATE OF REVISION OF THE TEXT