Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Xalacom 50 micrograms/ml + 5 mg/ml, eye drops, solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml solution contains latanoprost 50 micrograms and timolol maleate 6.8 mg equivalent to 5 mg timolol.

Excipient(s) with known effect:
Benzalkonium chloride,
Disodium phosphate anhydrous (E339ii),
Sodium dihydrogen phosphate monohydrate (E339i).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution.

Product imported from Greece, Lithuania and Belgium
The solution is a clear, colourless liquid.

4 CLINICAL PARTICULARS

As per PA23055/008/001

5 PHARMACOLOGICAL PROPERTIES

As per PA23055/008/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride
Benzalkonium chloride
Sodium dihydrogen phosphate monohydrate (E339i)
Disodium phosphate anhydrous (E339ii)
Hydrochloric acid solution (for adjustment to pH 6.0)
Sodium hydroxide solution (for adjustment to pH 6.0)
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 concomitantly with Xalacom, 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 opening of container: 4 weeks

6.4 Special precautions for storage

Before first opening: Store in a refrigerator (2°C - 8°C)
After first opening: Do not store above 25°C.
Use within 4 weeks (see section 6.3).
Keep the bottle in the outer carton in order to protect from light.

6.5 Nature and contents of container

Dropper container (5ml) with a screw cap and tamper evident overcap.
Each bottle contains 2.5 ml eye drop solution.
Pack sizes: 1 × 2.5 ml

6.6 Special precautions for disposal and other handling

The tamper evident overcap should be removed before use.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/406/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 17th of April 2015

10 DATE OF REVISION OF THE TEXT

February 2024