

# 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 and Lithuania*

The solution is a clear, colourless liquid.

## 4 CLINICAL PARTICULARS

As per PA0822/139/001

## 5 PHARMACOLOGICAL PROPERTIES

As per PA0822/139/001

## 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 shall be the date shown on the container and outer package of the product on the market in the country of origin.

After opening of container: 4 weeks

### 6.4 Special precautions for storage

Store in a refrigerator (2°C – 8°C)

Opened bottle: Do not store above 25°C.

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: 17<sup>th</sup> of April 2015

### **10 DATE OF REVISION OF THE TEXT**

March 2020