

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Xalatan 50 micrograms/ml eye drops, solution

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

100ml eye drops solution contains 5mg latanoprost

One drop contains approximately 1.5 micrograms latanoprost.

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

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Eye drops, solution

*Product imported from: Italy & UK (as Latanoprost and as Xalatan)*

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.

Shelf life after opening of container: 4 weeks.

### **6.4 Special precautions for storage**

Product imported from Italy (as Xalatan) and UK (as Latanoprost)

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 UK (as Xalatan)

Store at room temperature (below 25°C)

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

Use within four weeks of opening.

### **6.5 Nature and contents of container**

Dropper container with either a screw cap and tamper evident overcap or with a screw cap and tamper evident ring, in a cardboard carton.

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**

Imbat Limited  
Unit L2  
North Ring Business Park  
Santry  
Dublin 9  
Ireland

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1151/075/001

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 24<sup>th</sup> October 2008

**10 DATE OF REVISION OF THE TEXT**

January 2019