Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Xalatan 0.005% w/v eye drops solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of eye drops solution contains latanoprost 50 micrograms (0.005%w/v).
One drop contains approximately 1.5 micrograms latanoprost.
Excipient: Benzalkonium chloride 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 Latanaprost 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
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

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 and UK (as Latanaprost)
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^{o}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

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Imbat Limited
Unit L2
North Ring Business Park
Santry
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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA 1151/075/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 24th October 2008

10 DATE OF REVISION OF THE TEXT

August 2017