Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Xalatan 50 micrograms/ml eye drops, solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

100 ml eye drops solution contains 5 mg latanoprost.
One drop contains approximately 1.5 micrograms latanoprost.

Excipient(s) with known effect
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 the United Kingdom
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

Benzalkonium chloride
Sodium 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

Before first opening: The shelf life expiry date for this product shall be the date shown on the bottle and outer package of the product on the market in the country of origin.

After first opening of container: 4 weeks

6.4 Special precautions for storage

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

Do not store above 25 °C and use within four weeks after first opening the bottle.

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 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

LTT Pharma Limited
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United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/160/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 24th July 2015

10 DATE OF REVISION OF THE TEXT

August 2018