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 0.005g latanoprost.

One drop contains approximately 1.5 micrograms latanoprost.

Excipient: Benzalkonium chloride is included as a preservative.

For a 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 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 for this product shall be the date shown on the blister and outer package of the product on the market in the country of origin.

After first opening: 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 of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements

7 PARALLEL PRODUCT AUTHORISATION HOLDER

LTT Pharma Limited
Unit 18
Oxleasow Road
East Moons Moat
Redditch
Worcestershire
B98 0RE
UK

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 2016