Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Betagan 0.5% w/v Eye Drops, Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml solution contains 5.0 mg levobunolol hydrochloride, equivalent to 4.4 mg levobunolol.

Excipient (s): Contains benzalkonium chloride 0.04 mg/ml.

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Eye Drops, Solution

Product imported from the UK:
A clear, colourless to light yellow solution.

4 CLINICAL PARTICULARS

As per PA0148/040/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0148/040/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Poly (vinyl alcohol)
Benzalkonium chloride
Sodium metabisulphite (E223)
Sodium chloride
Disodium edetate
Sodium phosphate dibasic heptahydrate
Potassium dihydrogen phosphate
Sodium hydroxide (to adjust ph) or
Hydrochloric acid (to adjust ph)
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

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 opening: 1 month

6.4 Special precautions for storage

Do not store above 25^{o}C. Keep the bottle in the outer carton in order to protect from light.

6.5 Nature and contents of container

Bottle and dropper tip made of low density polyethylene. The cap is either a "traditional", high impact, polystyrene cap or a high impact, polystyrene compliance cap (C-Cap) with an external rotating sleeve indicating daily dosage status.

Both have a safety seal to ensure integrity.

5 ml Bottles.

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
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/056/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

The date of first authorisation: 26th August 2011

10 DATE OF REVISION OF THE TEXT

August 2015