# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Betoptic 0.5% w/v Eye Drops, Solution.

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Betaxolol 0.5% w/v (as hydrochloride).
Excipients with known effects: Benzalkonium chloride 0.01% w/v.

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 pale yellow sterile, eye drops solution.

## 4 CLINICAL PARTICULARS

As per PA0290/061/001

## 5 PHARMACOLOGICAL PROPERTIES

As per PA0290/061/001

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Disodium edetate
Sodium chloride
Benzalkonium chloride
Sodium hydroxide (for pH-adjustment)
Hydrochloric acid (for pH-adjustment)
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: 4 weeks

### 6.4 Special precautions for storage

Do not store above 25°C. Store in the original package in order to protect from light.
Discard remaining contents 4 weeks after first opening.

## 6.5 Nature and contents of container

LDPE bottles, with LDPE plug Drop- Tainer and blue polystyrene or polypropylene cap, containing 5ml of solution.

## 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

PPA1562/047/001

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

Date of the first authorisation: 13th May 2011

## 10 DATE OF REVISION OF THE TEXT

October 2015