

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 5mg levobunolol hydrochloride.

Excipient(s): Contains benzalkonium chloride.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution.

Product imported from 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 of this product shall be the date shown on the bottle and outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 25°C.

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

6.5 Nature and contents of container

White bottle and dropper tip made of low density polyethylene. The cap is either a green or white polystyrene cap or a white, polystyrene compliance cap (C-Cap®) with an external rotating sleeve indicating daily dosage status. Each have a safety seal to ensure integrity.

The bottle contains 5ml of solution.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

B & S Healthcare
Unit 4, Bradfield Road
Middlesex HA4 0NU
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1328/137/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 3rd September 2010

10 DATE OF REVISION OF THE TEXT

April 2015