

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: Benzalkonium chloride 0.01% w/v.

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution.

Product imported from: UK

A clear, colourless to pale yellow, sterile eye drops solution.

4 CLINICAL PARTICULARS

As per PA 0290/061/001

5 PHARMACOLOGICAL PROPERTIES

As per PA 0290/061/001

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 of this product shall be the date shown on the container 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

A plastic bottle with a screw 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

Imbat Limited
Unit L2, North Ring Business Park
Santry
Dublin 9

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA 1151/170/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 4th November 2011

10 DATE OF REVISION OF THE TEXT

July 2015