

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Brolene 0.1% w/v Eye Drops Solution

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Propamidine isetionate 0.1% w/v.

Excipient(s) with known effect

Benzalkonium chloride

For the full list of excipients, see section 6.1

## 3 PHARMACEUTICAL FORM

Eye drops, solution (eye drops)

*Product imported from the United Kingdom*

A clear, colourless, sterile, aqueous solution.

## 4 CLINICAL PARTICULARS

As per PA0540/094/001

## 5 PHARMACOLOGICAL PROPERTIES

As per PA0540/094/001

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Ammonium chloride  
Sodium chloride  
Benzalkonium chloride  
Sodium hydroxide  
Water for injections

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

Unopened: The shelf life expiry date for this product shall be the date shown on the bottle label and outer package of the product on the market in the country of origin.

Opened: The drops should be discarded 28 days after first opening for domiciliary use or after 7 days when used under hospital conditions.

#### **6.4 Special precautions for storage**

Store below 25°C.

#### **6.5 Nature and contents of container**

Plastic bottle with tamper-proof cap containing 10 ml of solution, packaged in a cardboard carton.

#### **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**

Lexon (UK) Ltd  
Unit 18  
Oxleasow Road  
East Moons Moat  
Redditch  
Worcestershire B98 0RE  
United Kingdom

### **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1097/046/001

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

Date of first authorisation: 4<sup>th</sup> May 2018

### **10 DATE OF REVISION OF THE TEXT**