

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Beta-Prograne 160 mg Prolonged-Release Capsules

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains Propranolol Hydrochloride 160 mg

Excipient - Sucrose and Sulfur Dioxide (E220)

For a full list of excipients, see section 6.1

## 3 PHARMACEUTICAL FORM

Prolonged-release capsule, hard.

*Product imported from the UK*

White size 2 hard gelatin capsules containing white uniform spherical microgranules.

## 4 CLINICAL PARTICULARS

As per PA22720/002/001

## 5 PHARMACOLOGICAL PROPERTIES

As per PA22720/002/001

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Neutral microgranules  
Povidone  
Ethylcellulose  
Talc  
Gelatine  
Titanium dioxide (E171)  
Sulfur dioxide (E220)

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on the blister 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.  
Store in the original package in order to protect from light and moisture.

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

Blister packs:

PVC: Colourless 250 micron thickness.

Aluminium: 25 microns thickness.

28 capsules per pack, 14 capsules per blister strip.

## **6.6 Special precautions for disposal and other handling**

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**

PPA1097/018/002

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

Date of first authorisation: 17<sup>th</sup> July 2020

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