Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Beta-Prograne 160mg Prolonged-Release Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains Propranolol Hydrochloride 160 mg

Excipient(s) with known effect
Sucrose and Sulphur Dioxide (E220)

For the 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 PA0644/001/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0644/001/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Neutral microgranules
Povidone
Ethylcellulose
Talc
Gelatine
Titanium Dioxide (E171)
Sulphur 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

Rebox containing 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

LTT Pharma Limited
Unit 18
Oxleasow Road
East Moons Moat
Redditch
Worcestershire
B98 0RE
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/182/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 2nd September 2016

10 DATE OF REVISION OF THE TEXT

April 2018