

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Half Beta-Propranolol 80 mg Prolonged-Release Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains Propranolol Hydrochloride 80 mg
Excipients with known effects - Contains Sucrose and Sulphur Dioxide (E220)

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Prolonged release capsules, hard.

Product imported from UK

Capsules with opaque white cap and colourless, transparent body containing white microgranules.

4 CLINICAL PARTICULARS

As per PA22720/002/002

5 PHARMACOLOGICAL PROPERTIES

As per PA22720/002/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Neutral microgranules.
Povidone.
Ethylcellulose.
Talc.

Capsule components:

Gelatin.
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

Blister packs: 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
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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1097/018/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26th September 2017

10 DATE OF REVISION OF THE TEXT