Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Nebilet 5 mg tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Nebilet tablet contains 5 mg of nebivolol (as nebivolol hydrochloride): 2.5 mg of SRRR-nebivolol (d-nebivolol) and 2.5 mg of RSSS-nebivolol(or-nebivolol).

Excipient with known effect: lactose monohydrate

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet.

Product imported from the Czech Republic

White, round, cross-scored tablet.
The tablet can be divided in equal quarters.

4 CLINICAL PARTICULARS

As per PA0865/005/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0865/005/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polysorbate 80
Hypromellose 2506/15
Lactose monohydrate
Maize starch
Croscarmellose sodium
Microcrystalline cellulose
Silica colloidal anhydrous
Magnesium stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product is the date shown on the container and outer package of the product in the country of origin.

6.4 Special precautions for storage

This medicinal product does not require any special storage precautions.

6.5 Nature and contents of container

Tablets are provided in blister packs (PVC/aluminium blister).
Pack sizes of 28 tablets

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

PCO Manufacturing
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/327/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14th March 2014

10 DATE OF REVISION OF THE TEXT

February 2016