

## Summary of Product Characteristics

### 1 NAME OF THE MEDICINAL PRODUCT

NEBILET 5 mg tablets

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Excipients: lactose monohydrate

For a full list of excipients, see section 6.1.

### 3 PHARMACEUTICAL FORM

Tablets.

*Product imported from Italy, the UK and the Netherlands:*

White, round, cross-scored tablets.

The tablets 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

Lactose monohydrate

Maize starch

Croscarmellose sodium

Microcrystalline cellulose

Colloidal anhydrous silica

Magnesium stearate

#### 6.2 Incompatibilities

Not applicable

#### 6.3 Shelf life

The shelf life expiry date of this product shall be the date shown on the container and outer package of the product on the market 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**

Product imported from Italy:  
Re-boxed carton containing blister strips.  
Pack size: 28 tablets.

Product imported from the UK:  
Over-labelled outer cardboard carton containing blister strips.  
Pack size: 28 tablets.  
Re-boxed carton containing blister strips.  
Pack size: 28 tablets.

Product imported from the Netherlands:  
Over-labelled outer cardboard carton containing blister strips.  
Pack size: 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**

Imbat Limited  
Unit L2  
North Ring Business Park  
Santry  
Dublin 9

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1151/083/001

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

Date of First Authorisation: 10<sup>th</sup> October 2008

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

July 2015