

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Cardicor 1.25mg Film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 1.25 mg bisoprolol fumarate.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet

The product imported from Italy, The United Kingdom and Germany:

White, round film-coated tablets

4 CLINICAL PARTICULARS

As per PA0654/007/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0654/007/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Product imported from Italy and the United Kingdom

Tablet Core:

Silica, Colloidal anhydrous

Magnesium Stearate

Crospovidone

Pregelatinised maize starch

Maize starch

Microcrystalline cellulose

Calcium hydrogen phosphate, anhydrous.

Film coating:

Dimeticone

Talc

Macrogol 400

Titanium dioxide (E171)

Hypromellose.

Product imported from Germany

Silica, Colloidal anhydrous

Magnesium (stearate, palmitate, oleat)

Crospovidone

Pregelatinised starch

Maize starch

Microcrystalline cellulose
Calcium hydrogen phosphate
Dimeticone
Talc
Macrogol 400
Titanium dioxide (E171)
Hypromellose

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

Do not store above 25°C.

6.5 Nature and contents of container

The immediate container is a blister, which is packaged in an outer carton.
Pack size: 28 or 30 tablets.
Not all pack sizes may be marketed.

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/204/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25th January 2008

10 DATE OF REVISION OF THE TEXT

March 2016