

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Cardicor 1.25mg Film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 1.25mg of bisoprolol fumarate.
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-Coated Tablet.

Product imported from the UK

White, round Film-Coated Tablets with no markings

4 CLINICAL PARTICULARS

As per PA0654/007/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0654/007/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Silica colloidal anhydrous
Magnesium stearate
Crospovidone
Pregelatinised maize starch
Maize starch
Microcrystalline cellulose
Anhydrous 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

Cardboard outer containing blister strip. Pack size 28.

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

PPA1151/048/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation 2nd May 2008

10 DATE OF REVISION OF THE TEXT

April 2015