

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Cardicor 1.25 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 1.25 mg bisoprolol fumarate.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet

Product imported from the UK

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

Tablet core:

Silica, Colloidal anhydrous

Magnesium stearate

Crospovidone

Pregelatinised maize starch

Maize Starch

Microcrystalline cellulose

Calcium hydrogen phosphate, (anhydrous)

Film coating:

Dimethicone

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 container is a blister, which is made of a polyvinylchloride base film and an aluminium cover foil.
Pack sizes: 28 tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

LTT Pharma Limited
Unit 18,
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Redditch,
Worcestershire B98 0RE,
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/142/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23rd January 2015.

10 DATE OF REVISION OF THE TEXT