

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Capoten 50 mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 50mg captopril.

Excipients with known effect: Lactose monohydrate

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet.

Product imported from the UK:

Slightly mottled, white, oval and biconvex, engraved with ‘Squibb’ and ‘482’ on one side, with a breakline on the other.

Product imported from Spain:

Slightly mottled, white, oval and biconvex, engraved with ‘Squibb’ and ‘482’ on one side, with a breakline on the other or white, oval, biconvex tablets with "50" engraved on one side and scored on the other side.

4 CLINICAL PARTICULARS

As per PA0002/039/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0002/039/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose
Maize starch
Microcrystalline cellulose
Stearic acid

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for 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.

Store in the original package in order to protect from moisture.

6.5 Nature and contents of container

Blister packs containing 30 and 56 tablets contained in an outer cardboard carton.

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
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/002/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28 September 1988

Date of last renewal: 28 September 2008

10 DATE OF REVISION OF THE TEXT

July 2015