

## Summary of Product Characteristics

### 1 NAME OF THE MEDICINAL PRODUCT

Capoten 25 mg Tablets

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 25mg captopril.

Excipients with known effect: lactose monhydrate

For a full list of excipients, see section 6.1.

### 3 PHARMACEUTICAL FORM

Tablet.

*Product imported from the UK:*

Slightly mottled, white, square tablets engraved 'Squibb' and '452' on one side and have quadrisect bars on the other.

*Product imported from Spain:*

Slightly mottled, white, square tablets engraved 'Squibb' and '452' on one side and have quadrisect bars on the other or slightly mottled, white, oval, biconvex tablets with "25" engraved on one side and scored on the other side."

### 4 CLINICAL PARTICULARS

As per PA0002/039/001

### 5 PHARMACOLOGICAL PROPERTIES

As per PA0002/039/001

### 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**

Blisters in a cardboard carton containing 56 and 60 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  
Ireland

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA0465/002/001

## **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