Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Zestril 5 mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains lisinopril dihydrate equivalent to 5 mg anhydrous lisinopril.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet

Product imported from Portugal:
Round, pink, uncoated, biconvex tablets with a heart shape and "5" on one side and bisected on the other side. Diameter 6mm. The tablet can be divided into equal halves.

4 CLINICAL PARTICULARS

As per PA23140/002/001

5 PHARMACOLOGICAL PROPERTIES

As per PA 23140/002/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Mannitol
Calcium Hydrogen Phosphate dihydrate
Red Iron Oxide (E172)
Maize Starch
Pregelatinised Starch
Magnesium Stearate

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 30°C

6.5 Nature and contents of container

Aluminium/PVC-PVDC, Aluminium/PVC or Aluminium/Aluminium foil blister packs of 28 tablets.

6.6 Special precautions for disposal and other handling

No special requirements

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing Ltd.
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/066/005

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11th October 2013

10 DATE OF REVISION OF THE TEXT

July 2022