Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Zestril 10mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains lisinopril dihydrate equivalent to 10 mg anhydrous lisinopril.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablets

Product sourced in the UK and The Netherlands
Pink, round biconvex uncoated tablets, impressed with a heart shape plus ‘10’ on one side and plain on the other or pink, round biconvex uncoated tablets, impressed with a heart shape plus '10 Zestril' on one side and plain on the other.

4 CLINICAL PARTICULARS

As per PA1019/026/002

5 PHARMACOLOGICAL PROPERTIES

As per PA1019/026/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Product sourced in The UK and The Netherlands:
Mannitol (E421)
Calcium hydrogen phosphate dihydrate
Red Iron oxide (E172)
Maize starch
Pregelatinised maize 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 30ºC.

6.5 Nature and contents of container

Blister packs of 14, 28 and 30 tablets.

Not all pack sizes may be marketed.

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

PPA0465/066/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13 July 2001
Date of last renewal: 13 July 2006

10 DATE OF REVISION OF THE TEXT

September 2020