

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Zestril 20 mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains lisinopril dihydrate equivalent to 20mg anhydrous lisinopril.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet.

Product sourced in Greece:

Pink, round biconvex uncoated tablets, impressed with a heart shape plus '20 Zestril' on one side and plain on the other.

Product sourced in the UK:

Pink, round biconvex tablets, impressed with a heart shape plus '20' on one side and plain on the other.

Product sourced in The Netherlands:

Pink, round biconvex uncoated tablets impressed with a heart shape plus '20 Zestril' on one side and a break line on the other side or Pink round biconvex tablets impressed with a heart shape plus '20' on one side and plain on the other.

Product source in Spain

Pink, round biconvex uncoated tablets, impressed with a heart shape plus '20 Zestril' on one side and a break line on the other side.

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

4 CLINICAL PARTICULARS

As per PA1019/026/003

5 PHARMACOLOGICAL PROPERTIES

As per PA1019/026/003

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Calcium hydrogen phosphate dihydrate

Magnesium stearate

Maize starch

Mannitol (E421)

Iron oxide (E172)

Pregelatinised starch

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.
Store in the original package.

6.5 Nature and contents of container

Overlabelled blister packs of 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

PPA0465/066/004

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13 July 2001
Date of last renewal: 07 November 2010

10 DATE OF REVISION OF THE TEXT

September 2020