

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lisinopril 5 mg tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 5 mg lisinopril as lisinopril dihydrate.

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Tablet.

Product imported from the UK:

White, round, flat tablets scored on both sides. The tablet can be divided into equal halves.

4 CLINICAL PARTICULARS

As per PA1380/007/002

5 PHARMACOLOGICAL PROPERTIES

As per PA1380/007/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Manitol (E421)
Calcium hydrogen phosphate dihydrate (E341)
Pregelatinised maize starch
Croscarmellose sodium
Magnesium stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product is the date shown on the blister strips and outer carton of the product as marketed in the country of origin.

6.4 Special precautions for storage

Do not store above 25°C. Store in the original package.

6.5 Nature and contents of container

Blister packs of 28 tablets contained in an over labelled outer cardboard carton.

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

WPR Healthcare Ltd
Unit 10
Ashbourne Business Park
Rath
Ashbourne
Co. Meath

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0565/046/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14th October 2011

10 DATE OF REVISION OF THE TEXT

May 2015