

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lansoprazole 15mg Gastro-resistant Capsules, hard

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 15 mg of lansoprazole.

Excipient(s) with known effect: sucrose

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Gastro-resistant capsule, hard.

Product imported from the UK:

A hard gelatin capsule with an opaque white cap and opaque white body, filled with white to beige micropellets. The capsules have been marked using black ink with the letter “L” on the cap and the number “15” on the body.

4 CLINICAL PARTICULARS

As per PA1986/008/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1986/008/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Gastro-resistant pellets:

Sugar spheres (sucrose, corn starch)

Sodium starch glycolate

Sodium laurilsulfate

Povidone

Trisodium phosphate

Hypromellose

Methacrylic acid-ethyl acrylate copolymer (1:1)

Triethyl citrate

Titanium dioxide (E171)

Talc

Capsule shells:

Titanium dioxide (E171)

Water

Ink:

Shellac

Ethyl alcohol anhydrous

Isopropyl alcohol

Propylene glycol
N-butyl alcohol
Ammonium hydroxide
Potassium hydroxide
Black iron oxide (E172)

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 30°C

6.5 Nature and contents of container

Blister strips in an outer carton. Pack size: 28 tablets.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

WPR Healthcare Limited
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0565/063/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16th February 2017

10 DATE OF REVISION OF THE TEXT