

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lansoprazole 15 mg Gastro-resistant capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 15 mg of lansoprazole

Excipients with known effect:

Each 15 mg capsule contains sucrose

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gastro-resistant capsules

Product imported from the UK;

Gastr-resistant capsule, with opaque yellow cap and body, containing pellets with enteric coating.

4 CLINICAL PARTICULARS

As per PA0577/065/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0577/065/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

maize starch

sucrose

sodium laurilsulphate

meglumine

mannitol (E421)

hypromellose

macrogol

talc

polysorbate

titanium dioxide (E171)

methacrylic acid-ethyl acrylate co-polymer

capsule shell:

gelatin

titanium dioxide (E171)

water

quinolone yellow (E104)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product is 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 25°C. Store in the original container in order to protect from moisture

6.5 Nature and contents of container

Blister pack: 28 film-coated tablets in a cardboard box.

6.6 Special precautions for disposal

Any unused product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0565/057/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 15th of May 2015

10 DATE OF REVISION OF THE TEXT