

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lansoprazole 30mg Gastro-resistant Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 30 mg of lansoprazole

Excipients:
Each capsule contains 129.6 mg sucrose (in sugar spheres)

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Gastro-resistant capsule, hard (gastro-resistant capsule).

Product imported from United Kingdom:
Hard, cellulose capsules with a white opaque cap marked with “L” in black ink and a white opaque body marked with “30” in black ink, filled with white to beige micropellets.

4 CLINICAL PARTICULARS

As per PA0749/135/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0749/135/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Sugar spheres (sucrose and maize starch)
- Sodium starch glycolate (type A)
- Sodium laurilsulfate
- Povidone (K30)
- Potassium oleate
- Oleic acid
- Hypromellose
- Methacrylic acid - ethyl acrylate copolymer 1:1
- Triethyl citrate
- Titanium dioxide (E171)
- Talc
- Carrageenan
- Potassium chloride
- Carnauba wax

Printing ink:
Shellac (lacca)
Propylene glycol
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 shall be the date shown on the blister strips and the outer carton of the product as marketed in the country of origin.

6.4 Special precautions for storage

Store below 30°C.

6.5 Nature and contents of container

Cardboard outer carton containing blister strips
Pack size: 28 capsules

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Imbat Limited
Unit L2, North Ring Business Park
Santry
Dublin 9
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/206/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25th November 2013

10 DATE OF REVISION OF THE TEXT

February 2016