

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lansoprazole 15mg Orodispersible Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each orodispersible tablet contains 15 mg of lansoprazole.
Excipients of known effect: lactose, aspartame and sucrose.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Orodispersible tablet

Product imported from the United Kingdom:

White to off-white, flat bevelled round tablet debossed with "15" on one side of the tablet and plain on the other side.
Each orodispersible tablet contains white to greyish gastroresistant granules.

4 CLINICAL PARTICULARS

As per PA0749/024/003

5 PHARMACOLOGICAL PROPERTIES

As per PA0749/024/003

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sugar spheres (sucrose and maize starch)
Hypromellose
Talc (extra fine)
Magnesium carbonate
Methacrylic acid-ethyl acrylate copolymer (1:1)
Triethyl citrate
Titanium dioxide (E171)
Colloidal anhydrous silica
Lactose monohydrate
Maize starch
Aspartame
Magnesium stearate
Strawberry flavour

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

Do not store above 25°C.
Store in the original package to protect from moisture.

6.5 Nature and contents of container

Cardboard outer carton containing blister strips
Pack size: 28 orodispersible tablets

6.6 Special precautions for disposal and other handling

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

PPA1151/206/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25th November 2013

10 DATE OF REVISION OF THE TEXT

June 2015