

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Losec MUPS 10 mg gastro-resistant tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gastro-resistant tablet contains 10.3 mg omeprazole magnesium equivalent to 10 mg omeprazole.

Excipient(s) with known effect: sucrose.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gastro-resistant tablet.

Product imported from Belgium:

Losec 10 mg gastro-resistant tablets: Light-pink, oblong, biconvex, film-coated tablets engraved with logo on one side and 10 mg on the other side.

4 CLINICAL PARTICULARS

As per PA2239/009/001

5 PHARMACOLOGICAL PROPERTIES

As per PA2239/009/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cellulose microcrystalline,
glyceryl monostearate 40-55,
Hydroxypropylcellulose,
Hypromellose,
Magnesium stearate,
Methacrylic acid-ethyl acrylate copolymer (1:1) dispersion 30 per cent,
Sugar spheres,
Synthetic paraffin (NF),
Macrogol (polyethylene glycol 6000),
Polysorbate 80,
Crospovidone,
sodium hydroxide (for pH-adjustment),
Sodium stearyl fumarate,
Talc,
Triethyl citrate,
Iron oxide,
Titanium dioxide

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 package in order to protect from moisture.

6.5 Nature and contents of container

Carton containing 4 blister strips (7 tablets per strip).

Pack size: 28 tablets.

6.6 Special precautions for disposal

No special requirements

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing Ltd.
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/423/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 29th October 2021

10 DATE OF REVISION OF THE TEXT

July 2023