

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Losec MUPS 40 mg gastro-resistant tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gastro-resistant tablet contains omeprazole magnesium equivalent to 40 mg omeprazole.

Excipient(s) with known effect

Each gastro-resistant tablet contains sucrose.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gastro-resistant tablet.

Product imported from the United Kingdom

Dark red-brown, oblong, biconvex, film-coated tablets, engraved with  on one side and 40 mg on the other side.

4 CLINICAL PARTICULARS

As per PA0970/044/008

5 PHARMACOLOGICAL PROPERTIES

As per PA0970/044/008

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cellulose Microcrystalline
Glycerol 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 E172
Titanium dioxide E171

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on the blister 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

Blisters of 7 tablets.

6.6 Special precautions for disposal

No special requirements

7 PARALLEL PRODUCT AUTHORISATION HOLDER

IMED Healthcare Ltd
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/123/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14th June 2018

10 DATE OF REVISION OF THE TEXT