

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 41.3 mg omeprazole magnesium equivalent to 40 mg omeprazole.


Excipient(s) with known effect: Contains sucrose.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gastro-resistant tablet.

Product imported from UK

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

4 CLINICAL PARTICULARS

As per PA1019/011/003

5 PHARMACOLOGICAL PROPERTIES

As per PA1019/011/003

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 E172,
Titanium dioxide E171

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product shall be 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

Over-labelled outer carton containing blister package. Pack size 7

Blister package re-boxed into cartons: Pack size 14

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Imbat Limited
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Santry
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Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/007/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13th March 2020

10 DATE OF REVISION OF THE TEXT