

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Losec MUPS 20mg Gastro-resistant Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gastro-resistant tablet contains 20.6 mg omeprazole magnesium equivalent to 20 mg omeprazole.
Excipient with known effect: contains sucrose (sugar spheres)
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gastro-resistant tablet

Product imported from the UK:
Pink, oblong, biconvex, gastro-resistant, film-coated tablets engraved with logo on one side and 20 mg on the other side containing enteric coated pellets.

4 CLINICAL PARTICULARS

As per PA0970/044/007.

5 PHARMACOLOGICAL PROPERTIES

As per PA0970/044/007.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Microcrystalline cellulose
- Glyceryl monostearate
- Hydroxypropylcellulose
- Hypromellose
- Magnesium stearate
- Methylacrylic acid-ethyl acrylate co-polymer (1:1) dispersion 30 per cent
- Sugar spheres
- Synthetic paraffin
- Macrogol
- Polysorbate
- Crospovidone
- Sodium stearyl fumarate
- Sodium hydroxide (for pH adjustment)
- Talc
- Triethyl citrate
- Iron oxide (colour E172)
- Titanium dioxide (colour 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 packaging of the product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 25°C.

Keep the tablets in the foil blister in the original container in order to protect from moisture.

6.5 Nature and contents of container

Losec MUPS Tablets are provided in press-through Aluminium-Polyamide-PVC/Aluminium foil calendarised blister packs. Packs of 28 tablets.

6.6 Special precautions for disposal

No special requirements

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Clear Pharmacy
157-173 Roden Street
Belfast BT12 5QA
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1596/027/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 15th of October 2010.

10 DATE OF REVISION OF THE TEXT

December 2016