

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Losec MUPS 20 mg gastro-resistant tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gastro-resistant tablet contains 20.6 mg omeprazole magnesium equivalent to 20 mg omeprazole

Excipients with known effect: sucrose (contained in sugar spheres).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gastro-resistant tablet.

Product imported from Belgium

Pink, oblong, biconvex, film-coated tablets engraved with a logo on one side and '20 mg' on the other side containing enteric coated pellets.

4 CLINICAL PARTICULARS

As per PA2239/009/002

5 PHARMACOLOGICAL PROPERTIES

As per PA2239/009/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose
Glycerol monostearate
Hyprolose
Hypromellose
Magnesium stearate
Methacrylic acid co-polymer C
Sugar spheres (contain sucrose)
Paraffin
Macrogol
Polysorbate
Crospovidone
Sodium stearyl fumarate
Sodium hydroxide*
Talc
Triethyl citrate
Iron oxide (E172)
Titanium dioxide (E171)
* May be added as a pH adjuster

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product is the date shown on the blister and 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 in order to protect from moisture.

6.5 Nature and contents of container

Belgium: Blisters in an outer cardboard carton. Pack size: 28 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

PPA1463/141/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 8th September 2006

Date of last renewal: 8th September 2011

10 DATE OF REVISION OF THE TEXT

January 2022