

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 20mg omeprazole (as 20.6mg omeprazole magnesium).

Excipients: Sucrose (contained in sugar spheres)

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gastro-resistant tablet.

Product imported from the UK, Belgium and Germany:

Pink, oblong, biconvex tablets engraved with a logo on one side and '20mg' on the other side.

4 CLINICAL PARTICULARS

As per PA0970/044/007

5 PHARMACOLOGICAL PROPERTIES

As per PA0970/044/007

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Product imported from the UK and Belgium:

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

Product imported from Germany:

Microcrystalline cellulose
Glycerol monostearate 40-55
Hydroxypropylcellulose
Hypromellose
Magnesium stearate
Methacrylic acid - ethyl acrylate copolymer (1:1)
Sugar spheres (sucrose and maize starch)
Hard Paraffin
Macrogol 6000
Polysorbate 80
Crospovidone
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 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

UK & Belgium: Blisters in an outer cardboard carton. Pack size: 28 tablets
Germany: Aluminium blisters in cardboard wallets in an outer cardboard carton. Pack size 30 or 60 tablets.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Imbat Limited
Unit L2
North Ring Business Park
Santry
Dublin 9
Ireland

7 PARALLEL PRODUCT AUTHORISATION HOLDER

IMED Healthcare Ltd.
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
09 October 2020

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

October 2020