

## 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: 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 logo 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,  
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 blister strip 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**

Carton containing 2 blister strips (7 tablets per strip).  
Pack size: 14 tablets

### **6.6 Special precautions for disposal**

No special requirements.

## **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

PCO Manufacturing  
Unit 10, Ashbourne Business Park  
Rath  
Ashbourne  
Co. Meath  
Ireland

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA0465/423/002

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 25<sup>th</sup> August 2017

## **10 DATE OF REVISION OF THE TEXT**