

## 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 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 UK:*

Pink, oblong, biconvex, film-coated tablets, engraved with 20mg on one side and a logo 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

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 is 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**

Blister packs of 7 tablets in a carton. Pack size: 28 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**

PPA0465/423/001

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

Date of first authorisation: 20<sup>th</sup> January 2017

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