

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Nexium 20 mg Gastro-Resistant Tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gastro resistant tablet contains 20 mg esomeprazole (as magnesium trihydrate)

Excipient(s) with known effect:

Each gastro-resistant tablet contains Sucrose

For the full list of excipients, see section 6.1

## 3 PHARMACEUTICAL FORM

Gastro resistant tablet

*Product imported from theUKtheNetherlands, Germany, Greece, France, Belgium, Italy, Romania and Croatia:*  
Light pink, oblong, biconvex, film-coated tablets engraved '20mg' on one side and 'A/EH' on the other.

## 4 CLINICAL PARTICULARS

As per PA2242/013/003

## 5 PHARMACOLOGICAL PROPERTIES

As per PA2242/013/003

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Glycerol monostearate 40-55  
Hydroxypropyl cellulose  
Hypromellose  
Iron oxide (reddish-brown, yellow) (E172)  
Magnesium stearate  
Methacrylic acid ethyl acrylate copolymer (1:1) dispersion 30 per cent  
Microcrystalline cellulose  
Synthetic paraffin  
Macrogol  
Polysorbate 80  
Crospovidone  
Sodium stearyl fumarate  
Sugar spheres (sucrose and maize starch)  
Talc  
Titanium dioxide (E171)  
Triethyl citrate.

### 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 30°C.

Store in the original package (blister) in order to protect from moisture.

### **6.5 Nature and contents of container**

Blister or wallet packs of 28, 30 or 56 Tablets.

Not all pack sizes may be marketed.

### **6.6 Special precautions for disposal and other handling**

No special requirements for disposal.

*Administration through gastric tube:*

1. Put the tablet into an appropriate syringe and fill the syringe with approximately 25 mL water and approximately 5 mL air. For some tubes, dispersion in 50 mL water is needed to prevent the pellets from clogging the tube.

2. Immediately shake the syringe for approximately 2 minutes to disperse the tablet.

3. Hold the syringe with the tip up and check that the tip has not clogged.

4. Attach the syringe to the tube whilst maintaining the above position.

5. Shake the syringe and position it with the tip pointing down. Immediately inject 5-10 mL into the tube. Invert the syringe after injection and shake (the syringe must be held with the tip pointing up to avoid clogging of the tip).

6. Turn the syringe with the tip down and immediately inject another 5-10 mL into the tube. Repeat this procedure until the syringe is empty.

7. Fill the syringe with 25 mL of water and 5 mL of air and repeat step 5 if necessary to wash down any sediment left in the syringe. For some tubes, 50 mL water is needed.

## **7 MARKETING AUTHORISATION HOLDER**

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

## **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

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

**8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA0465/083/001

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

Date of first authorisation: 08 February 2002

Date of last renewal: 08 February 2007

**10 DATE OF REVISION OF THE TEXT**

June 2020