Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Esomeprazole 20 mg gastro-resistant tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains: 20 mg esomeprazole as esomeprazole magnesium (amorphous).

Excipient with known effect:
Each tablet contains sucrose.

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Gastro-resistant tablet
Product imported from the United Kingdom:
Light brick red to brown coloured, oval, biconvex, film-coated tablets with ‘E5’ debossed on one side and plain on other side.

4 CLINICAL PARTICULARS

As per PA 408/81/1

5 PHARMACOLOGICAL PROPERTIES

As per PA 408/81/1

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablets core
Sugar spheres (sucrose and maize starch)
Hydroxypropyl cellulose (E463)
Crospovidone (TypeB)
Povidone K30
Macrogol-400
Talc (E553b)
Hypromellose phthalate (HP-55S)
Hypromellose phthalate (HP-50)
Diethylphthalate
Macrogol 6000
Crospovidone (TypeA)
Microcrystalline cellulose (PH 101)
Microcrystalline cellulose (PH 112)
Sodium stearyl fumarate

Coat
Macrogol-4000
Opadry 03B86651 Brown
(HPMC 2910/Hypromellose 6cP (E464)

Titanium Dioxide (E171)
Macrogol/PEG 400
Talc (E553b)
Iron Oxide red (E172))

6.2 Incompatibilities

Not applicable

6.3 Shelf life

The shelf life expiry date of this product shall be the date shown on the container and the outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

Store below 30°C
Store in the original package (blister) in order to protect from moisture

6.5 Nature and contents of container

Blisters of 28 tablets in a cardboard carton.

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements

Administration through gastric tube
1. Put the tablet into an appropriate syringe and fill the syringe with approximately 25 ml water and approximately 5mL 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 step5 if necessary to wash down any sediment left in the syringe. For some tubes, 50 ml water is needed.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

WPR Healthcare Limited
Unit 10 Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0565/053/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14th November 2014

10 DATE OF REVISION OF THE TEXT