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 22.3 mg esomeprazole magnesium trihydrate equivalent to 20mg esomeprazole.
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 the UK, Italy, Belgium & Greece:
Light pink, oblong, biconvex tablet engraved '20mg' on one side and 'A/EH' on the other side.

4 CLINICAL PARTICULARS

As per PA1019/012/002

5 PHARMACOLOGICAL PROPERTIES

As per PA1019/012/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol monostearate 40-55
Hyprolose
Hypromellose
Iron oxide (reddish-brown & yellow) (E172)
Magnesium stearate
Methacrylic acid ethyl acrylate copolymer (1.1) dispersion 30 per cent
Microcrystalline cellulose
Synthetic paraffin
Macrogols
Polysorbate 80
Crospovidone
Sodium stearyl fumerate
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 blister strips and outer carton of the product as marketed in the country of origin.

6.4 Special precautions for storage

Do not store above 30°C.
Store in the original package in order to protect from moisture.

6.5 Nature and contents of container

Product imported from the UK, Italy, Belgium
Over-labelled outer carton containing blister package. Pack size 28

Blister package reboxed into cartons: Pack size 28

Product imported from Greece
Over-labelled outer carton containing blister package. Pack size 14, 28

Blister package reboxed into cartons: Pack size 28

Not all pack sizes may be marketed.

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 for disposal.
Not to be crushed or chewed;
Swallow whole
or
Administration through gastric tube

1. Put the tablet into an appropriate syringe and fill the syringe with approximately 25mL of water and approximately 5mL of air. For some tubes, dispersion in 50mL 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 5-10mL 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 5-10mL into the tube. Repeat this procedure until the syringe is empty.
7. Fill the syringe with 25mL of water and 5mL of air and repeat step 5 if necessary to wash down any sediment left in the syringe. For some tubes, 50mL water is needed.

7 MARKETING AUTHORISATION HOLDER

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

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 22nd September 2006

Date of last renewal: 22nd September 2011

10 DATE OF REVISION OF THE TEXT

October 2019