Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Nexium 40 mg gastro-resistant tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:
40 mg esomeprazole (as magnesium trihydrate).

Excipient(s) with known effect:
Each gastro-resistant tablet contains 30 mg sucrose

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Gastro-resistant tablet

Product imported from the United Kingdom:

A pink, oblong, biconvex, film-coated tablet engraved 40 mg on one side and A EI on the other side.

4 CLINICAL PARTICULARS

As per PA0970/027/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0970/027/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol monostearate 40-55
Hyprolose
Hypromellose
Iron oxide (reddish-brown 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 for this product shall be the date shown on the blister and outer package of the re-boxed product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 30ºC.

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

6.5 Nature and contents of container

Aluminium blister package. Blister packs in carton of 28 tablets.

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.

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 PARALLEL PRODUCT AUTHORISATION HOLDER

LTT Pharma Limited
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United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/065/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 30th September 2011

10 DATE OF REVISION OF THE TEXT

March 2018