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 20 mg 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 Croatia

A light pink, oblong, biconvex, film-coated tablet engraved 20mg on one side and A EH on the other side.

4 CLINICAL PARTICULARS

As per PA2242/013/002

5 PHARMACOLOGICAL PROPERTIES

As per PA2242/013/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol monostearate 40-55,
hyprolose,
hypromellose,
iron oxide (reddish-brown and yellow) (E 172),
magnesium stearate,
methacrylic acid ethyl acrylate copolymer (1:1) dispersion 30 per cent,
cellulose microcrystalline,
synthetic paraffin,
macrogol,
polysorbate 80,
crospovidone,
sodium stearyl fumarate,
sugar spheres (sucrose and maize starch),
talc,
titanium dioxide (E 171),
triethyl citrate.

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 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 in order to protect from moisture.

6.5 Nature and contents of container

Blister packs of 28 tablets

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 PARALLEL PRODUCT AUTHORISATION HOLDER

Lexon Pharmaceuticals (Ireland) Limited
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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA23176/015/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 27th October 2017

10 DATE OF REVISION OF THE TEXT

November 2022