Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Nexium 40 mg gastro-resistant tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gastro-resistant tablet contains 40mg esomeprazole (as magnesium trihydrate)

Excipient(s) with known effect:

Each gastro resistant table contains sucrose.
For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Gastro-resistant tablet.

Product imported from France, and Greece:
Pink, oblong, biconvex , film-coated gastro-resistant tablet engraved '40mg' on one side and 'A/EI' 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
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 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 in order to protect from moisture.

6.5 Nature and contents of container

France and Greece: Aluminium blisters with cardboard reinforcement (blister wallet) in an over-labelled cardboard carton containing 28 tablets.

6.6 Special precautions for disposal and other handling

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

IMED Healthcare Ltd.
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8 MARKETING AUTHORISATION NUMBER

PPA1463/002/002

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/002/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 11th April 2008

10 DATE OF REVISION OF THE TEXT