

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Pantoprazole 40 mg gastro-resistant tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gastro-resistant tablet contains 40 mg pantoprazole (as sodium sesquihydrate).
For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Gastro-resistant tablet (tablet).

Product imported from the United Kingdom:

Yellow, oval, biconvex film-coated tablets imprinted with "P 40" in brown ink on one side.

4 CLINICAL PARTICULARS

As per PA1421/001/003

5 PHARMACOLOGICAL PROPERTIES

As per PA1421/001/003

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core:

Sodium carbonate, anhydrous
Mannitol (E421)
Crospovidone
Povidone K90
Calcium stearate

Coating:

Hypromellose
Povidone K25
Titanium dioxide (E171)
Yellow iron oxide (E172)
Propylene glycol
Methacrylic acid-ethyl acrylate copolymer (1:1)
Polysorbate 80
Sodium laurilsulfate
Triethyl citrate

Printing Ink:

Shellac
Red iron oxide (E172)
Black iron oxide (E172)
Yellow iron oxide (E172)
Ammonia solution, concentrated

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

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Blisters of 28 gastro-resistant tablets in a cardboard carton.

6.6 Special precautions for disposal

No special requirements.

Any unused product should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing
Unit 10,
Ashbourne Business Park,
Rath,
Ashbourne,
Co. Meath,
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/403/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 24th November 2014

10 DATE OF REVISION OF THE TEXT

March 2016