Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Protium 20 mg Gastro-Resistant Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 20 mg pantoprazole (as sodium sesquihydrate).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gastro-resistant tablet (tablet)

Product imported from Spain, United Kingdom, Italy and Hungary.

Yellow, oval biconvex film-coated tablet imprinted with ‘P20’ in brown ink on one side.

4 CLINICAL PARTICULARS

As per PA1547/009/002

5 PHARMACOLOGICAL PROPERTIES

As per PA1547/009/002

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)
Titanium dioxide (E171)
Antifoam DC 1510 (dimeticone emulsion)

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

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Blister packs of 28 tablets.

6.6 Special precautions for disposal

No special requirements.
Any unused product or waste material 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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/071/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 27 July 2001

Date of last renewal: 27 July 2006

10 DATE OF REVISION OF THE TEXT

January 2017