Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Protium 20 mg gastro-resistant tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gastro-resistant tablet contains 20 mg of pantoprazole (as sodium sesquihydrate).

Excipient

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gastro-resistant coated tablet.

Product imported from Poland:
Yellow, oval biconvex coated tablets marked ‘P20’ on one side.

4 CLINICAL PARTICULARS

As per PA1421/001/002

5 PHARMACOLOGICAL PROPERTIES

As per PA1421/001/002

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)
Ammonia solution, concentrated

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product is the date shown on the blister strips and outer carton of the product as marketed 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 (ALU/ALU blister) without cardboard reinforcement.

28 gastro-resistant 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

IMED Healthcare Ltd.
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/008/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 3rd November 2008

10 DATE OF REVISION OF THE TEXT

June 2016