

## Summary of Product Characteristics

### 1 NAME OF THE MEDICINAL PRODUCT

Protium 40 mg gastro-resistant tablets

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gastro-resistant tablet contains 40 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 the Poland:*

Yellow, oval biconvex coated tablets marked 'P40' 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 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**

28 gastro-resistant tablets  
Blister (ALU/ALU blister) without cardboard reinforcement.

## **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**

PPA1463/008/002

## **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