

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).

Excipients: Soya lecithin

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gastro-resistant tablet (tablet).

Product imported from Hungary:

A yellow, oval biconvex film-coated tablet imprinted with “P20” in brown ink on one side.

4 CLINICAL PARTICULARS

As per PA1547/009/002

4.3 Contraindications

Protium tablets contain soya lecithin. If you are allergic to peanut or soya, do not use this medicinal product.

4.4 Special warnings and precautions for use

Soya oil

This medicinal product contains soya oil. If the patient is allergic to peanut or soya, do not use this medicinal product (see section 4.3).

5 PHARMACOLOGICAL PROPERTIES

As per PA1547/009/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Anhydrous sodium carbonate
- Mannitol
- Crospovidone
- Povidone k90
- Calcium stearate
- Hypromellose 2910
- Povidone k25
- Propylene glycol
- Methacrylic acid-ethylacrylate-copolymer
- Polysorbate 80
- Sodium lauril sulfate

Triethyl citrate
Titanium dioxide (E171)
Yellow iron oxide (E172)
Shellac
Red iron oxide (E172)
Black iron oxide (E172)
Soya lecithin
Polydimethylsiloxane

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 packaging 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 packaged in a cardboard carton.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

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

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Clear Pharmacy
157-173 Roden Street
Belfast
BT12 5QA
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1596/032/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11th February 2011

10 DATE OF REVISION OF THE TEXT

January 2017