

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 pantoprazole sodium sesquihydrate)

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gastro-resistant tablet

Product imported from the UK:

Yellow, oval, biconvex, smooth film-coated tablet

4 CLINICAL PARTICULARS

As per PA0749/144/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0749/144/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:

Disodium Phosphate Anhydrous

Mannitol (E421)

Cellulose Microcrystalline

Croscarmellose Sodium

Magnesium Stearate (vegetable)

Tablet coating:

Hypromellose

Triethyl citrate

Sodium Starch Glycolate (Type A)

Methacrylic acid-Ethyl acrylate copolymer (1:1)

Yellow Iron Oxide(E172)

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

Do not store above 30°C.

6.5 Nature and contents of container

Blister strips in an outer carton. Pack size: 28 tablets.

6.6 Special precautions for disposal

No special requirements.

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

7 PARALLEL PRODUCT AUTHORISATION HOLDER

WPR Healthcare Limited
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0565/064/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16th February 2017

10 DATE OF REVISION OF THE TEXT