

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Omeprazole 10 mg Gastro-resistant Capsules, hard

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains omeprazole 10 mg.
Excipient(s) with known effect: Also contains sucrose.
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gastro-resistant Capsules, hard.

Product imported from the UK;

Omeprazole 10 mg Gastro-resistant hard Capsules

Each capsule consists of an orange body and red cap. The capsule is marked with the letter 'O' on the cap and with the number '10' on the body. The capsule contains white to off-white micropellets.

4 CLINICAL PARTICULARS

As per PA0749/160/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0749/160/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sugar spheres (sucrose and corn starch)
Sodium starch glycolate
Sodium laurilsulfate
Povidone K-30
Trisodium phosphate dodecahydrate
Hypromellose
Methacrylic acid - ethyl acrylate copolymer
Triethyl citrate
Sodium hydroxide
Titanium dioxide (E171)
Talc

Capsule – Red iron oxide (E172), Erythrosine (E127), Titanium dioxide (E171), Water, Gelatin, Quinoline yellow (E104)

Printing Ink

Shellac
Polyvinylpyrrolidone
Propylene glycol
Sodium Hydroxide
Titanium Dioxide (E171)

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

Blisters: Do not store above 30°C. Store in the original package in order to protect from moisture.

6.5 Nature and contents of container

Omeprazole Capsules are provided in Aluminium/Aluminium foil blister packs of 28 capsules.

6.6 Special precautions for disposal

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

PPA0565/056/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 12th June 2015

10 DATE OF REVISION OF THE TEXT