Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Zantac 300 mg Film-coated Tablets.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film coated tablet contains 300 mg ranitidine (as hydrochloride).

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated Tablet.

White, capsule-shaped tablets with ‘GX EC3’ on one side and plain on the other side.

4 CLINICAL PARTICULARS

As per 1077/013/004.

5 PHARMACOLOGICAL PROPERTIES

As per 1077/013/004.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet Core
Microcrystalline cellulose (E460)
Croscarmellose sodium
Magnesium stearate

Film Coat
Hypromellose
Titanium dioxide (E171)
Triacetin

6.2 Incompatibilities

Not applicable

6.3 Shelf life

The shelf-life expiry date for this product shall be 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

Do not store above 25°C. Store in the original package in order to protect from moisture.

6.5 Nature and contents of container

Blister packs of 30 tablets contained in an overlabelled outer 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.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing Limited
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/033/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 27 November 1998

Date of last renewal: 27 November 2008

10 DATE OF REVISION OF THE TEXT

February 2017