# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Zantac 150mg Film-coated Tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 150mg ranitidine (as hydrochloride).

For full list of excipients, *see section 6.1*.

## 3 PHARMACEUTICAL FORM

Film-coated tablet.

*Product imported from the Netherlands and the UK:*
White, round, biconvex tablets, engraved 'GXEC2' on one side and plain on the other.

## 4 CLINICAL PARTICULARS

As per PA1077/013/003

## 5 PHARMACOLOGICAL PROPERTIES

As per PA1077/013/003

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Microcrystalline cellulose
Magnesium stearate
Hypromellose
Titanium dioxide (E171)
Triacetin

### 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 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/foil packs containing 60 tablets.

## 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
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath

## 8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/033/001

## 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 30 May 1995

Date of last renewal: 30 May 2010

## 10 DATE OF REVISION OF THE TEXT

December 2017