Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Zantac 300mg 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

Product imported from the UK:
White, round tablets engraved ‘GXEC3’ on one side and plain on the other.

4 CLINICAL PARTICULARS

As per PA1077/013/004

5 PHARMACOLOGICAL PROPERTIES

As per PA1077/013/004

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core
Microcrystalline cellulose
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 blister and outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

Foil blister strips of 5 tablets in and overlabelled outer carton. 30 tablet pack.

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

LTT Pharma Ltd.
Unit 18, Oxleasow Road
East Moons Moat
Redditch
Worcestershite
B98 0RE
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/051/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 3rd June 2011

10 DATE OF REVISION OF THE TEXT

August 2016