Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Zantac 150 mg/10 ml Syrup

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 10 ml of syrup contains ranitidine hydrochloride equivalent to 150 mg of ranitidine

Excipients with known effect: each 10ml of Zantac syrup contains:
Approximately 7.5% (800mg) Ethanol equivalent to 750 mg of pure ethanol
Propyl parahydroxybenzoate (E216)
Butyl parahydroxybenzoate
Sorbitol

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Syrup.
Product imported from the Netherlands:
A clear, colourless to pale yellow liquid with an odour of mint.

4 CLINICAL PARTICULARS

As per PA1077/013/002

5 PHARMACOLOGICAL PROPERTIES

As per PA1077/013/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydroxypropylmethylcellulose (E464)
Ethanol
Propyl parahydroxybenzoate (E216)
Butyl parahydroxybenzoate
Potassium dihydrogen phosphate
Disodium hydrogen phosphate
Sodium chloride
Sodium saccharin
Sorbitol (E420)
Peppermint oil flavouring agent
Purified water

6.2 Incompatibilities

Dilution of Zantac syrup with syrup BP or sorbitol solution is not recommended as this may result in precipitation.
In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

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.

Once opened: 28 days.

6.4 Special precautions for storage

Do not store above 25°C. Do not freeze.

6.5 Nature and contents of container

Amber Type III glass bottle fitted with propylene screw cap and a polyester liner or a polypropylene child resistant cap and a LDPE liner containing 300 ml of syrup. A double ended 5 ml/2.5 ml polypropylene spoon is included.

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

Dilution of Zantac Syrup with Syrup B.P. or Soribitol Solution is not recommended as this may result in precipitation.
No special requirements

7 MARKETING AUTHORISATION HOLDER

LTT Pharma Limited
Unit 18, Oxleasow Road
East Moons Moat
Redditch
Worcestershire B98 0RE
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/051/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26th September 2014

10 DATE OF REVISION OF THE TEXT