Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Ranitidine 150mg/10ml Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ranitidine Hydrochloride 167.5mg/10ml (equivalent to Ranitidine 150mg/10ml)

Ethanol = 810mg/10ml
Sorbitol = 1.4g/10ml
Sodium = 22 mg/10 ml

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Oral Solution

Product imported from the UK:
A straw coloured liquid with odour of mint

4 CLINICAL PARTICULARS

As per PA0312/010/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0312/010/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Disodium hydrogen phosphate anhydrous (E339)
Sodium dihydrogen phosphate dihydrate
Saccharin sodium (E954)
Sorbitol solution 70% (E420)
Ethanol
Garden mint flavour
Purified water

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.

1 month after first opening the bottle.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Bottle: Amber (Type III) glass.
Closure: HDPE, EPE wadded, tamper evident, child resistant closure.

Pack Size: 300ml

6.6 Special precautions for disposal

Not applicable.

7 MARKETING AUTHORISATION HOLDER

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

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8 MARKETING AUTHORISATION NUMBER

PPA1562/130/001

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/130/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10th October 2014