Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

TRITACE 1.25 mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Tablets

Each tablet contains ramipril 1.25 mg

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Tablets

Product imported from the United Kingdom

White to almost white oblong tablet with score line, upper stamp 1.25 and company logo, lower stamp HMN and 1.25.

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

4 CLINICAL PARTICULARS

As per PA0540/084/005

5 PHARMACOLOGICAL PROPERTIES

As per PA0540/084/005

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hypromellose
Pregelatinized maize starch
Microcrystalline cellulose
Sodium stearyl fumarate

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

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Packs of 28, tablets in PVC/Alu blisters

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

Any unused product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/118/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 4th July 2014

10 DATE OF REVISION OF THE TEXT

October 2016