Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Triapin 5mg/5mg prolonged release tablet

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 5 mg of felodipine and 5 mg of ramipril.
Each tablet contains 51.5 mg lactose anhydrous.
For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Prolonged-release tablet

Product imported from Italy:

Triapin 5mg/5mg tablets are circular (diameter approx. 9 mm), apricot coloured, biconvex and engraved H/OE on one side and marked 5 on the other side.

4 CLINICAL PARTICULARS

As per PA0540/082/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0540/082/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cellulose microcrystalline
Hyprolose
Hypromellose
Iron oxides E172
Lactose anhydrous
Macrogol 6000
Macrogolglycerol hydroxystearate
Maize starch
Paraffin
Propyl gallate
Sodium aluminium silicate
Sodium stearyl fumarate
Titanium dioxide E 171

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 ºC.

6.5 Nature and contents of container

PVC/PVDC blisters: 28 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

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/128/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 17th October 2014

10 DATE OF REVISION OF THE TEXT

April 2015