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 lactose anhydrous. Also contains polyoxyl 40 hydrogenated castor oil.

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Prolonged release tablets.

Product imported from Italy:
Circular (diameter approx 9 mm), reddish/brown coloured, biconvex and engraved H/OE on one side and marked 5 on the other side.

4 CLINICAL PARTICULARS

As per PA0540/082/002

4.4 Special warnings and precautions for use

Lactose
This product contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Polyoxyl 40 hydrogenated castor oil
This product contains polyoxyl 40 hydrogenated castor oil. It may cause stomach upset or diarrhoea.

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
Polethylene glycol
Polyoxyl 40 hydrogenated castor oil
Maize starch
Paraffin
Propyl gallate
Sodium aluminium silicate
Sodium stearyl fumarate
Titanium dioxide E171

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product shall be the date shown on the bottle 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 in an outer cardboard carton

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing
Unit 10, Ashbourne Business Park
Rath, Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/332/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14th February 2014

10 DATE OF REVISION OF THE TEXT

October 2018