

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Triapin 5mg/5 mg, prolonged release tablets

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.

Each tablet also contains hydrogenated castor oil.

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Prolonged release tablet

Product imported from the Italy.

Triapin 5mg/5mg prolonged release tablets are reddish-brown and have “H/OE” marked on one side and “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

Hypolose

Hypromellose

Iron oxides (E172)

Lactose anhydrous

Macrogol 6000

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 is the date shown on the blister and outer carton of the product as marketed in the country of origin.

6.4 Special precautions for storage

Do not store above 25°C

6.5 Nature and contents of container

Blisters
28 tablets

6.6 Special precautions for disposal

No special requirements

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Primecrown 2010 Limited
4/5 Northolt Trading Estate
Belvue Road
Northolt
Middlesex
UB5 5QS
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1633/042/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 11th March 2016

10 DATE OF REVISION OF THE TEXT