Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Triapin 5 mg/5 mg prolonged release tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 5 mg of felodipine and 5 mg of ramipril

Excipient(s)with known effect: Each tablet contains lactose anhydrous and macrogolglycerol hydroxystearate (castor oil polyoxyl hydrogenated).

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), 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

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
Polyethylene Glycol
Macrogolglycerol hydroxystearate (castor oil polyoxyl hydrogenated)
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 container and outer carton 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 blisters: 28 tablets.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

IMED Healthcare Ltd.
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/098/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 15th August 2014

10 DATE OF REVISION OF THE TEXT

May 2022