

## Summary of Product Characteristics

### 1 NAME OF THE MEDICINAL PRODUCT

Triapin 2.5mg/2.5mg prolonged release tablet.

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 2.5 mg of felodipine and 2.5 mg of ramipril.

Each tablet contains lactose monohydrate and polyoxyl 40 hydrogenated castor oil.

For the full list of excipients, see section 6.1

### 3 PHARMACEUTICAL FORM

Prolonged release tablet.

*Product sourced from Portugal:*

Triapin 2.5mg/2.5mg tablets are circular, apricot coloured, biconvex and engraved H/OD on one side and marked 2.5 on the other side.

### 4 CLINICAL PARTICULARS

As per PA0540/082/001

#### 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.

*Palyoxyl 40 hydrogenated castor oil*

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

### 5 PHARMACOLOGICAL PROPERTIES

As per PA0540/082/001

### 6 PHARMACEUTICAL PARTICULARS

#### 6.1 List of excipients

Hydroxypropyl cellulose

Hydroxypropylmethyl cellulose  
Lactose anhydrous  
Maize starch  
Microcrystalline cellulose  
Polyethylene glycol  
Polyoxyl 40 hydrogenated castor oil  
Propyl gallate  
Sodium aluminium silicate  
Sodium stearyl fumarate  
Iron oxides E172  
Titanium dioxide E171  
Paraffin

## **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 package of the product on the market in the country of origin.

## **6.4 Special precautions for storage**

Do not store above 25°C.

## **6.5 Nature and contents of container**

Blister packs of 30 tablets.

## **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**

PPA0465/318/001

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 25<sup>th</sup> October 2013

**10 DATE OF REVISION OF THE TEXT**

October 2018