

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Plendil 5 mg Prolonged-Release Film-coated Tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains Felodipine 5mg and lactose anhydrous and polyoxyl 40 hydrogenated castor oil

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Prolonged-release, film-coated tablet.

*Product imported from Greece*

Pink, circular, biconvex, film-coated tablets, engraved A/FM on one side and ‘5’ on the other side.

## 4 CLINICAL PARTICULARS

As per PA0970/049/002

## 5 PHARMACOLOGICAL PROPERTIES

As per PA0970/049/002

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Polyoxyl 40 hydrogenated castor oil  
Hyprollose  
Propyl gallate,  
Hypromellose  
Sodium aluminium silicate  
Microcrystalline cellulose  
Lactose anhydrous  
Sodium stearyl fumarate  
Macrogol  
Titanium dioxide (E171)  
Iron oxide yellow (E172)  
Carnauba wax

### 6.2 Incompatibilities

Not applicable

### 6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on the blister and outer package of the product on the market in the country of origin.

## **6.4 Special precautions for storage**

Do not store above 30°C.

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

PVC/PVDC Blisters – Press-through blister package of PVC/PVDC form foil with an aluminium foil as enclosure web. Each blister strip contains 14 tablets. A single pack may contain 28 tablets as multiples of blisters of 14.

## **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**

PPA1562/157/001

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

Date of first authorisation: 15th of May 2015

## **10 DATE OF REVISION OF THE TEXT**