

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Plendil 5 mg prolonged-release tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 5 mg felodipine

### Excipient(s) with known effect:

Each tablet contains lactose and macrogolglycerol hydroxystearate (also known as polyoxyl 40 hydrogenated castor oil).

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Prolonged-release, tablet.

*Product imported from Italy, Poland, Romania and Greece*

Pink, circular, biconvex, tablets engraved A/FM on one side and '5' on the other side.

## 4 CLINICAL PARTICULARS

As per PA2256/005/002

## 5 PHARMACOLOGICAL PROPERTIES

As per PA2256/005/002

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Product imported from Italy

Polyoxyl 40 hydrogenated castor oil

hydroxypropyl cellulose

propyl gallate

hypromellose

aluminum sodium silicate

microcrystalline cellulose

anhydrous lactose

sodium stearyl fumarate

polyethylene glycol 6000

titanium dioxide E171

iron oxide E172

carnauba wax

purified water

Product imported from Italy, Poland, Romania and Greece

Tablet Core:

Hydroxypropyl cellulose

Hypromellose 50 mPa·s

Hypromellose 10000 mPa·s

Lactose anhydrous

Macrogolglycerol hydroxystearate

Microcrystalline cellulose

Propyl gallate  
Sodium aluminium silicate  
Sodium stearyl fumarate

Coating:

carnauba wax  
iron oxide reddish-brown (E172)  
iron oxide yellow (E172)  
hypromellose 6 mPa·s  
macrogol 6000  
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 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 30 °C.

**6.5 Nature and contents of container**

Each pack contains 28 tablets in blisters of 14 or 30 tablets in a bottle.  
Not all pack sizes may be marketed.

**6.6 Special precautions for disposal**

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

**7 PARALLEL PRODUCT AUTHORISATION HOLDER**

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

**8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA0465/405/001

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

Date of first authorisation: 23<sup>rd</sup> January 2015  
Last updated: July 2021

**10 DATE OF REVISION OF THE TEXT**

September 2023