

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Plendil 10 mg prolonged-release tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 10 mg felodipine.

Excipients with known effect:

Each tablet contains lactose and macrogolglycerol hydroxystearate

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Prolonged-release tablet.

Product imported from Poland, Italy, Romania and Greece:

The tablet is reddish-brown, circular, biconvex, engraved A/FE on one side and 10 on the other side, with a diameter of 9 mm.

4 CLINICAL PARTICULARS

As per PA2256/005/002

5 PHARMACOLOGICAL PROPERTIES

As per PA2256/005/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core

Hydroxypropylcellulose
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 size 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

PPA0465/405/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25th August 2017
Last revised: October 2019

10 DATE OF REVISION OF THE TEXT

September 2023