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

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 *Greece*
The tablet is pink, circular, biconvex engraved A/Fm on one side and 5 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 blister and outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

PVC/PVDC/Aluminium blister

28 tablets (calendar blister pack)

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

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/183/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10th September 2021

10 DATE OF REVISION OF THE TEXT

September 2023