Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Plendil 10 mg Prolonged-Release Film-coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains Felodipine 10mg 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

Red-brown, circular, biconvex, film-coated tablets, engraved ‘A/FE’ on one side and 10 on the other side.

4 CLINICAL PARTICULARS

As per PA0970/049/003.

5 PHARMACOLOGICAL PROPERTIES

As per PA0970/049/003.

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 contains 14 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
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Worcestershire B98 0RE
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/157/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 15th of May 2015

10 DATE OF REVISION OF THE TEXT