Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Teveten 600 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains eprosartan mesylate equivalent to 600 mg eprosartan.

Excipient with known effect: lactose (as lactose monohydrate).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet

Product imported from Greece
Capsule-shaped, white, film-coated tablet marked "5046" on one side and no inscription on the other side.

4 CLINICAL PARTICULARS

PA2010/017/002

5 PHARMACOLOGICAL PROPERTIES

PA2010/017/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet Core:
Lactose monohydrate
Microcrystalline cellulose
Pregelatinised starch
Crospovidone
Magnesium stearate
Purified water

Tablet Coating:
Hypromellose (E464)
Titanium dioxide (E171)
Macrogol 400
Polysorbate 80 (E433)

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

Do not store above 25°C.

6.5 Nature and contents of container

PVC/AL blister packs of 28 tablets.

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/469/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26th March 2021

10 DATE OF REVISION OF THE TEXT