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(s)
Lactose monohydrate.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet

Product as imported from Czech Republic, Greece and Italy
White capsule shaped, tablets with “SOLVAY” engraved on one side and “5046” on the other OR white capsule shaped, blank on one side and engraved “5046” on the other.

4 CLINICAL PARTICULARS

As per PA2010/017/002

5 PHARMACOLOGICAL PROPERTIES

As per PA2010/017/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Microcrystalline cellulose
Pregelatinised starch
Crospovidone
Magnesium stearate

Film-coating
Hypromellose
Titanium dioxide (E171)
Macrogol 400
Polysorbate 80

Product imported from the the Czech Republic also contains OPADRY OY-S-9603

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product is 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 25 °C.

6.5 Nature and contents of container

Blister packs of 28 tablets contained in an outer cardboard carton.

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

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/147/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 05 August 2005

Date of last renewal: 05 August 2010

10 DATE OF REVISION OF THE TEXT

August 2018