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:
Each film-coated tablet contains lactose.
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet

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

4 CLINICAL PARTICULARS

As per PA2010/017/002

5 PHARMACOLOGICAL PROPERTIES

As per PA2010/017/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet Core:
Lactose
Microcrystalline cellulose
Pregelatinised starch
Crospovidone
Magnesium stearate

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 is the date shown on the container and outer carton of the product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 25°C.Keep the blister in the outer carton.

6.5 Nature and contents of container

Over-labelled cardboard carton containing 2 blister strips (14 tablets per strip).
Pack size of 28 tablets.

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

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/091/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 31st January 2014

10 DATE OF REVISION OF THE TEXT

March 2022