

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 600mg eprosartan (as eprosartan mesilate).

Excipient with known effect; lactose monohydrate.
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film coated tablet.

Product imported from Italy:
White capsule shaped, film-coated tablets with “5046” engraved on one side and plain on the other.

4 CLINICAL PARTICULARS

As per PA2007/014/002

5 PHARMACOLOGICAL PROPERTIES

As per PA2007/014/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Microcrystalline cellulose
Pregelatinised maize starch
Crospovidone
Magnesium stearate

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

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product is the date shown on the blister foil 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

White PVC/aluminium blister packs 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

B & S Healthcare
Unit 4, Bradfield Road
Ruislip
Middlesex HA4 0NU
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1328/174/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 5th November 2012

10 DATE OF REVISION OF THE TEXT

November 2015