

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Teveten 600mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains Eprosartan mesylate equivalent to 600mg Eprosartan
Excipient: contains lactose

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet

Product imported from UK and Italy
Capsule shaped, white, film-coated tablet marked “5046” on one side and plain on the other side.

4 CLINICAL PARTICULARS

PA2007/014/002

5 PHARMACOLOGICAL PROPERTIES

PA2007/014/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Product imported from the UK;
Tablet core:
Lactose
Microcrystalline Cellulose
Pregelatinised starch
Crospovidone
Magnesium stearate

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

Product imported from Italy;

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 strips and outer carton of the product as marketed in the country of origin.

6.4 Special precautions for storage

UK: Do not store above 25°C. Store in the original package.
Italy: Do not store above 25°C.

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

Imbat Limited
Unit L2
North Ring Business Park
Santry
Dublin 9

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA 1151/118/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 7th August 2009

10 DATE OF REVISION OF THE TEXT

December 2016