Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Konverge 40mg/10mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Konverge 40 mg/10 mg film-coated tablets:
Each film-coated tablet of Konverge contains 40 mg of olmesartan medoxomil and 10 mg of amlodipine (as amlodipine besilate).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet

Product imported from Greece

Brownish-red, round, film-coated tablet of 8mm with C77 debossed on one side.

4 CLINICAL PARTICULARS

As per PA0865/017/003

5 PHARMACOLOGICAL PROPERTIES

As per PA0865/017/003

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:
Starch, pregelatinised maize
Silicified microcrystalline cellulose (microcrystalline cellulose with colloidal silicon dioxide)
Croscarmellose sodium
Magnesium Stearate

Tablet coat:
Polyvinyl alcohol
Macrogol 3350
Talc
Titanium dioxide (E171)
Iron (III) oxide (E172).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for 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

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Blister strips of tablets in a cardboard outer container, in packs of 28 film-coated tablets.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

LTT Pharma Limited
Unit 18
Oxleasow Road
East Moons Moat
Redditch
Worcestershire
B98 0RE
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/175/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16th September 2016

10 DATE OF REVISION OF THE TEXT

July 2018