Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Konverge Plus 40 mg/5 mg/12.5 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 40 mg olmesartan medoxomil, 5 mg amlodipine (as amlodipine besilate) and 12.5 mg hydrochlorothiazide.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet

Product imported from Greece

Light yellow, round, film-coated tablet of 9.5 mm debossed C53 on one side.

4 CLINICAL PARTICULARS

As per PA0865/019/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0865/019/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:
Pregelatinized maize starch,
Silicified microcrystalline cellulose (microcrystalline cellulose and silica colloidal anhydrous),
Croscarmellose sodium,
Magnesium stearate

Film coat:
Polyvinyl alcohol,
Macrogol 3350,
Talc,
Titanium dioxide (E 171),
Yellow iron oxide (E 172)

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

Laminated polyamide / aluminium / polyvinyl chloride / aluminium blister over-labelled with silver label and re-packaged into cartons of 28 film-coated 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

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/174/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 2nd September 2016

10 DATE OF REVISION OF THE TEXT

November 2016