Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Konverge Plus 40 mg/10 mg/25 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 40 mg of olmesartan medoxomil, 10 mg amlodipine (as amlodipine besilate) and 25 mg hydrochlorothiazide.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet

Product imported from Greece
Greyish red, oval, film-coated tablet with 'C57' debossed on one side.

4 CLINICAL PARTICULARS

As per PA0865/019/005

5 PHARMACOLOGICAL PROPERTIES

As per PA0865/019/005

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core
Starch, pregelatinised maize
Silicified microcrystalline cellulose (microcrystalline cellulose and silica colloidal anhydrous)
Croscarmellose sodium
Magnesium stearate

Film coat
Polyvinyl alcohol
Macrogol 3350
Talc
Titanium dioxide (E 171)
Iron (III) oxide yellow (E 172)
Iron (III) oxide red (E172)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product shall be the date shown on the container 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 pack containing 28 film-coated tablets in a cardboard carton.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing Ltd.
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/421/005

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20th January 2017

10 DATE OF REVISION OF THE TEXT

January 2020