

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Konverge 40 mg/10 mg 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 Italy and Greece:

Brownish-red, round, film-coated tablet with 'C 77' 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 red (E172)

Iron (III) oxide yellow

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
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/313/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 2nd August 2013

10 DATE OF REVISION OF THE TEXT

December 2016