Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Konverge 20mg/5mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Konverge 20 mg/5 mg film-coated tablets:

Each film-coated tablet of Konverge contains 20 mg of olmesartan medoxomil and 5 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
White, round, film-coated tablet of 6mm with C73 debossed on one side.

4 CLINICAL PARTICULARS

As per PA0865/017/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0865/017/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:
Starch, pregelatinised maize
Silicified microcrystalline cellulose
Croscarmellose sodium
Magnesium stearate

Tablet coat:
Polyvinyl alcohol
Macrogol 3350
Talc
Titanium dioxide (E171)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product is the date shown on the container and outer carton 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

Aluminium / PVC / Aluminium blister.
Pack sizes: 28 film-coated tablets.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

IMED Healthcare Ltd
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/104/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 4th December 2015

10 DATE OF REVISION OF THE TEXT