

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Konverge 40 mg/10 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

The active substances are olmesartan medoxomil and amlodipine (as besilate).
Each tablet contains 40mg of olmesartan medoxomil and 10mg amlodipine (as besilate).

Excipients with known effect: None
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated Tablets
Product imported from Italy
Brownish-red, film-coated, round tablets with C77 on one side and plain on reverse.

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: pregelatinised maize starch, silicified microcrystalline cellulose, croscarmellose sodium and magnesium stearate.

Tablet coat: polyvinyl alcohol, macrogol 3350, talc, titanium dioxide (E171) and iron (III) oxide (E172).

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 as marketed in the country of origin.

6.4 Special precautions for storage

This medicinal product does not require any special storage condition.

6.5 Nature and contents of container

Cardboard outer carton containing blisters.
Pack size: 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

Imbat Limited
Unit L2
North Ring Business Park
Santry
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Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/255/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23rd October 2015

10 DATE OF REVISION OF THE TEXT