

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Inegy 10 mg / 40 mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 10mg ezetimibe and 40mg simvastatin.

Also contains Lactose monohydrate.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet

Product imported from Spain:

White to off-white capsule-shaped tablets with code “313” on one side.

4 CLINICAL PARTICULARS

As per PA0035/095/003

5 PHARMACOLOGICAL PROPERTIES

As per PA0035/095/003

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylated hydroxyanisole
Citric acid monohydrate
Croscarmellose sodium
Hypromellose
Lactose monohydrate
Magnesium stearate
Microcrystalline cellulose
Propyl gallate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product shall be the date shown on the blister and outer carton of the product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 30°C. Store in the original pack in order to protect from light and moisture.

6.5 Nature and contents of container

Push-through blisters of opaque polychlorotrifluoroethylene /PVC sealed to vinyl coated aluminum in packs of 28 tablets.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

B&S Healthcare
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Bradfield Road
Ruislip
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HA4 0NU
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1328/203/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st March 2013

10 DATE OF REVISION OF THE TEXT

March 2015