

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Inegy 10mg/40mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 10mg ezetimibe and 40mg of simvastatin.

Excipient(s) with known effect:

Each 10/40mg tablet contains lactose monohydrate.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet

Product imported from the UK, Italy and Greece:

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
Hyromellose
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 is 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

Do not store above 30°C.

Store in the original package in order to protect from moisture and light.

6.5 Nature and contents of container

Push through blisters of opaque polychlorotrifluoroethylene/PVC sealed to vinyl coated aluminium in packs of 28 or 30 tablets in an over-labelled outer carton.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

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

PPA0465/223/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19th June 2009

10 DATE OF REVISION OF THE TEXT

April 2016