

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Inegy 10 mg/40 mg tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Excipient(s) with known effect

Each 10 mg/40 mg tablet contains lactose monohydrate.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet

Product imported from Italy

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

4 CLINICAL PARTICULARS

As per PA1286/062/003

5 PHARMACOLOGICAL PROPERTIES

As per PA1286/062/003

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 is the date shown on the blister 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

Blisters of 30 tablets in an outer carton.

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing Ltd.
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/223/004

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14th December 2018

10 DATE OF REVISION OF THE TEXT

February 2021