

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Inegy 10 mg/20 mg tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 10 mg ezetimibe and 20 mg of simvastatin.

Excipient with known effect

Each 10 mg/20 mg tablet contains lactose monohydrate.

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Tablet

*Product imported from the United Kingdom, Greece and Italy*

White to off-white capsule-shaped tablets with code '312' on one side.

## 4 CLINICAL PARTICULARS

As per PA1286/062/002

## 5 PHARMACOLOGICAL PROPERTIES

As per PA1286/062/002

## 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**

*Product imported from Italy*

Blisters of 30 tablets in an outer carton

*Product imported from United Kingdom and Greece*

Blisters of 28 tablets in an overlabelled 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**

PPA0465/223/001

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 19<sup>th</sup> June 2009

## **10 DATE OF REVISION OF THE TEXT**

January 2019