

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Ezetrol 10 mg Tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 10mg of ezetimibe.  
Excipient(s) with known effect:  
Each tablet contains lactose monohydrate.

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Tablet

*Product imported from the UK, Greece, the Czech Republic and Poland:*  
White to off-white, capsule-shaped tablets debossed with ‘414’ on one side.

## 4 CLINICAL PARTICULARS

As per PA 0035/096/001.

## 5 PHARMACOLOGICAL PROPERTIES

As per PA 0035/096/001.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Croscarmellose sodium  
Lactose monohydrate  
Magnesium stearate  
Microcrystalline cellulose  
Povidone (K29-32)  
Sodium laurilsulfate

### 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.

## **6.5 Nature and contents of container**

2 x blister strips containing 14 tablets contained in a carton or an over-labelled outer carton.

Pack size: 28 tablets (sourced from the UK, Greece & The Czech Republic)

3 x blister strips containing 10 tablets or 2 x blisters containing 15 tablets contained in a carton and an over-labelled carton.

Pack size: 30 tablets (sourced from Greece & The Czech Republic).

Not all pack sizes may be marketed.

## **6.6 Special precautions for disposal and other handling**

No special requirements.

## **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

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

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA0465/227/001

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

Date of first authorisation: 31<sup>st</sup> July 2009

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

May 2016