Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Ezetrol 10 mg tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 10 mg 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 PA1286/061/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1286/061/001

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, Czech Republic & Poland)
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 Ltd.
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/227/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 31st July 2009

10 DATE OF REVISION OF THE TEXT

October 2020