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 Czech Republic & UK

White to off-white, capsule-shaped tablets debossed with '414' on one side

4 CLINICAL PARTICULARS

As per PA0035/096/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0035/096/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Croscarmellose sodium
Lactose monohydrate
Magnesium stearate
Microcrystalline cellulose
Povidone
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 blister strip and outer carton of the product as marketed in the country of origin.

6.4 Special precautions for storage

Do not store above 30ºC.
Store in the original package in order to protect from moisture.

6.5 Nature and contents of container

Cardboard outer containing PVC blisters

Product imported from Czech Republic
Pack size: 30 tablets

Product imported from UK
Pack size: 28 tablets

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Imbat Limited
Unit L2
North Ring Business Park
Santry
Dublin 9
Ireland

8 MARKETING AUTHORISATION NUMBER

PPA1151/256/001

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/256/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21st October 2016

10 DATE OF REVISION OF THE TEXT

March 2020