Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Ezetrol 10 mg tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 10 mg ezetimibe.

Excipient(s) with known effect: lactose monohydrate

Ezetrol contains less than 1 mmol (23 mg) sodium per tablet

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet.

Product imported from *Czech Republic*.
White to off-white, capsule-shaped tablets, approximately 2.60 mm thick, debossed with "414" on one side.

4 CLINICAL PARTICULARS

As per PA23198/023/001

5 PHARMACOLOGICAL PROPERTIES

As per PA23198/023/001

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 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

Push-through blisters of clear polychlorotrifluoroethylene/PVC sealed to vinyl coated aluminium in packs of 30 tablets.

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

IMED Healthcare Ltd.
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/187/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18th February 2022

10 DATE OF REVISION OF THE TEXT

December 2022