Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Atozet 10 mg/80 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 10 mg of ezetimibe and 80 mg of atorvastatin (as atorvastatin calcium trihydrate).

Excipient(s) with known effect: lactose monohydrate

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet

Product imported from France:
Capsule-shaped, biconvex, white to off-white, film coated tablet with "357" debossed on one side.

4 CLINICAL PARTICULARS

As per PA23198/022/004

5 PHARMACOLOGICAL PROPERTIES

As per PA23198/022/004

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core
Ezetimibe Layer
Croscarmellose sodium
Lactose monohydrate
Magnesium stearate
Microcrystalline cellulose
Povidone
Sodium laurilsulfate

Atorvastatin Layer
Cellulose, microcrystalline
Lactose monohydrate
Hydroxypropylcellulose
Croscarmellose sodium
Polysorbate 80
Calcium carbonate
Magnesium stearate
Silica, colloidal anhydrous

Film coating
Hypromellose
Macrogol 8000
Titanium dioxide (E171)
Talc

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product shall be 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

Store in the original package in order to protect from oxygen.

6.5 Nature and contents of container

Packs of 30 film-coated tablets in aluminium blisters.

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

PPA1463/215/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 27th October 2023

10 DATE OF REVISION OF THE TEXT