

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 with known effect: lactose monohydrate.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Product imported from France:

Film-coated tablet.

Capsule-shaped, biconvex, white to off-white, film-coated, size 19.05 mm x 7.94 mm, "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

Cellulose, microcrystalline

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

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/470/004

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25th June 2021

10 DATE OF REVISION OF THE TEXT

October 2023