

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Atozet 10mg/10mg Film-coated tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 10 mg of ezetimibe and 10 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 "257" debossed on one side

## 4 CLINICAL PARTICULARS

As per PPA1463/215/003

## 5 PHARMACOLOGICAL PROPERTIES

As per PPA1463/215/003

## 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 blisters (aluminum/aluminum) (oPA/Al/PVC cavity with Al lid) with nitrogen purge.

## **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**

PPA1463/215/003

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 26<sup>th</sup> July 2024

## **10 DATE OF REVISION OF THE TEXT**