

Atrozemb 10//10 mg

Atrozemb 10/20 mg

Ezetimibe/ Atorvastatin

Film coated tablets

Approved
Dr. Salma
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Alaa M.

1 NAME OF THE MEDICINAL PRODUCT

Atrozemb 10/10 mg film coated tablet

Atrozemb 10/20 film coated tablet

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

ATROZEMB 10/10

Each film-coated tablet contains:

Atorvastatin calcium trihydrate 10.82 mg eq. to atorvastatin 10 mg + ezetimibe 10 mg

ATROZEMB 10/20

Each film-coated tablet contains:

Atorvastatin calcium trihydrate 21.64 mg eq. to atorvastatin 20 mg + ezetimibe 10 mg

Excipients with known effect:

Each 10 mg/10 mg film-coated tablet contains 90.05 mg of lactose monohydrate.

Each 10 mg/20 mg film-coated tablet contains 124.61 mg of lactose monohydrate.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

White to off white round biconvex unscored Film-coated table

4.1 Therapeutic indications

Prevention of Cardiovascular Events

ATROZEMB is indicated to reduce the risk of cardiovascular events in patients with coronary heart disease (CHD) and a history of acute coronary syndrome

(ACS), either previously treated with a statin or not.

Hypercholesterolaemia

ATROZEMB is indicated as adjunctive therapy to diet for use in adults with primary (heterozygous familial and non-familial) hypercholesterolaemia or mixed hyperlipidaemia where use of a combination product is appropriate

- patients not appropriately controlled with a statin alone
- patients already treated with a statin and ezetimibe
- *Homozygous Familial Hypercholesterolaemia (HoFH)*

ATROZEMB is indicated as adjunctive therapy to diet for use in adults with HoFH. Patients may also receive adjunctive treatments (e.g., low-density lipoprotein [LDL] apheresis).

4.2 Posology and method of administration

Posology

Hypercholesterolaemia and/or Coronary Heart Disease (with ACS History)

The patient should be on an appropriate lipid-lowering diet and should continue on this diet during treatment with ATROZEMB.

The dose range of ezetimibe/atorvastatin is 10/10 mg/day through 10/80 mg/day. The typical dose is 10/10 mg once a day. The patient's low-density lipoprotein cholesterol (LDL-C) level, coronary heart disease risk status, and response to current cholesterol-lowering therapy should be considered when starting therapy or adjusting the dose.

The dose of ezetimibe/atorvastatin should be individualised based on the known efficacy of the various dose strengths of ezetimibe/atorvastatin and the response to the current cholesterol-lowering therapy. Adjustment of dose should be made at intervals of 4 weeks or more.

Homozygous Familial Hypercholesterolaemia

The dose of ezetimibe/atorvastatin in patients with homozygous FH is 10/10 to 10/80 mg daily. Ezetimibe/atorvastatin may be used as an adjunct to other lipid-lowering treatments (e.g., LDL apheresis) in these patients or if such treatments are unavailable.

Co-administration with other medicines

Dosing of ezetimibe/atorvastatin should occur either ≥ 2 hours before or ≥ 4 hours after administration of a bile acid sequestrant.

In patients taking hepatitis C antiviral agents elbasvir/grazoprevir concomitantly with ezetimibe/atorvastatin, the dose of ezetimibe/atorvastatin should not exceed 10/20 mg/day.

Elderly

No dose adjustment is required for older patients.

Paediatric population