

Atrozemb
10/40 mg
10/80 mg
Ezetimibe/Atorvastatin
Film Coated Tablets.

النائب
ع.ع. / م.ع.

1. Name of the medicinal product

Atrozemb

2. Qualitative and quantitative composition

Atrozemb 10/40 mg

Each Film Coated Tablet contains

Atorvastatin calcium trihydrate 43.28 mg equivalent to Atorvastatin 40 mg+ Ezetimibe 10 mg.

Atrozemb 10/80 mg

Each Film Coated Tablet contains

Atorvastatin calcium trihydrate 86.56 mg equivalent to Atorvastatin 80 mg+ Ezetimibe 10 mg.

For a full list of excipients, see section 6.1

3. Pharmaceutical Form:

White to off -white oblong, biconvex unscored film coated tablets

4.1 THERAPEUTIC INDICATIONS

Prevention of cardiovascular disease

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.

Hypercholesterolemia

ATROZEMB is indicated as adjunctive therapy to diet in patients with primary (heterozygous familial and non-familial) hypercholesterolemia or mixed hyperlipidemia where use of a combination product is appropriate

- Patients not appropriately controlled with statin alone
- Patients Already treated with statin and ezetimibe
- Homozygous familial hypercholesterolemia (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

Hypercholesterolemia and /or coronary heart disease with (ACS history)

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

The dosage range of ezetimibe/atorvastatin is 10/10 mg/day through 10/80 mg/day, the typical dose is 10/10 mg once daily. 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 individualized 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 by intervals of 4 weeks or more.

Homozygous familial hypercholesterolemia

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 treatment (e.g., LDL apheresis) in these patients or if such treatments are unavailable.

Co- administrations 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 10-20mg/day

Elderly

No dose adjustment is required for older patients.