

EZEKEM 10 (EZETIMIBE TABLETS 10MG)

Ezetimibe Tablets 10 mg

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What EZEKEM is used for

EZEKEM is a tablet that contains mg of ezetimibe as the active ingredient.

- EZEKEM is a cholesterol-lowering medicine.
- EZEKEM is for patients whose cholesterol levels are too high and when diet alone cannot lower these levels adequately.
- EZEKEM reduces elevated total-cholesterol, LDL (bad) cholesterol and triglycerides and increases HDL (good) cholesterol.
- EZEKEM may be taken with other cholesterol-lowering medicines known as statins or alone, in addition to diet.
- EZEKEM may be taken with fenofibrate, another cholesterol-lowering medicine, in addition to diet.

How EZEKEM works

- EZEKEM works by decreasing the absorption of cholesterol in the small intestine. Statins and fenofibrate lower cholesterol in a different way; they work in the liver.
- EZEKEM adds to the cholesterol-lowering effect of statins and fenofibrate.

Why has my doctor prescribed EZEKEM?

Your doctor has prescribed EZEKEM to reduce the amount of cholesterol and triglycerides in your blood. Cholesterol is one of several fatty substances found in the bloodstream. Your total cholesterol is made up mainly of

LDL and HDL cholesterol.

LDL cholesterol is often called “bad” cholesterol because it can build up in the walls of your arteries forming plaque. Eventually this plaque build-up can lead to a narrowing of the arteries. This narrowing can slow or block blood flow to vital organs such as the heart and brain. This blocking of blood flow can result in a heart attack or stroke.

HDL cholesterol is often called “good” cholesterol because it helps keep the bad cholesterol from building up in the arteries and protects against heart disease.

Triglycerides are another form of fat in your blood that may increase your risk for heart disease.

How can high cholesterol be treated?

High cholesterol can be treated in two main ways:

Lifestyle Changes – including a cholesterol-lowering diet, increased physical activity, and weight management.

Medication – Cholesterol-lowering medicines are used together with lifestyle changes to help lower cholesterol. Your doctor has prescribed EZEKEM to help lower your cholesterol.

Before you use EZEKEM

It is important that you continue taking EZEKEM daily as prescribed by your doctor.

Even if you are taking medication to treat high cholesterol, it is important to have your cholesterol measured regularly. You should also know your cholesterol levels and goals.

Use in elderly

No special precautions.

Use in children

EZEKEM is not recommended in

children under age 10.

When you must not take it

Patients who are hypersensitive (allergic) to EZEKEM or any of its ingredients should not take EZEKEM.

Before you start to take it

Tell your doctor about:

Pregnancy: If you are pregnant or plan to become pregnant, EZEKEM may not be right for you.

Breast-feeding: If you are breast-feeding, EZEKEM may be passed in your milk to your baby.

Medical Problems or Allergies: Talk about any medical problems (including liver disease or liver problems) or allergies you have now or have had in the past.

Taking other medicines

You should always tell your doctor about all drugs that you are taking or plan to take, including those obtained without a prescription.

In particular, tell your doctor if you are taking medicine(s) with any of the following active ingredients:

- cyclosporin (often used in organ transplant patients)
- medicines with an active ingredient to prevent blood clots, such as warfarin or fluindione (anticoagulants)
- cholestyramine (also used to lower cholesterol), because it affects the way EZEKEM works
- fibrates (also used to lower cholesterol)

How to use EZEKEM

How much to take

Take one 10 mg tablet by mouth each day, at any time of day.

When to use it

- Take EZEKEM with or without food.

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- Your doctor may let you take EZEKEM along with other medicines, known as statins, or with another medicine known as fenofibrate, to help you better control your cholesterol
- If you are taking a statin or fenofibrate, EZEKEM can be taken at the same time as the other medicine.
- If your doctor has prescribed EZEKEM along with cholestyramine (a bile acid sequestrant) or any other bile acid sequestrant, EZEKEM should be taken at least 2 hours before or 4 hours after taking the bile acid sequestrant.
- Do not give EZEKEM to anyone else, even if they have the same symptoms or condition as you.

How long to use it

Continue taking your cholesterol-lowering medicines unless your doctor tells you to stop.

If you forget to use it

Try to take EZEKEM as prescribed. However, if you miss a dose, just resume the usual schedule of one tablet daily.

If you use too much (Overdose)

Take EZEKEM only as prescribed for you. If you take more EZEKEM than you were prescribed, contact your doctor or pharmacist

While you are using it

Things you must do

- EZEKEM should be taken as directed by your health care provider.
- Talk about any other medicines that you are taking or plan to take. Include those you can get without a prescription.
- Tell your doctor immediately if you become pregnant while taking this medication.

Things you must not do

- Do not take EZEKEM if you are hypersensitive (allergic) to

EZEKEM or any of its ingredients
Things to be careful of
Can I drive or operate machinery while using EZEKEM?

- There have been side effects reported with EZEKEM that may affect your ability to drive or operate machinery. Individual responses to EZEKEM may vary. (See Side effects)

Side effects

- EZEKEM was generally well tolerated. The side effects were usually mild and similar in type and frequency to side effects in patients who were given a placebo (a pill containing no medication). Side effects generally did not cause patients to stop taking EZEKEM.

- When used alone, the following side effects were reported:
 - Common: abdominal pain, diarrhea, flatulence, feeling tired.
 - Uncommon: elevations in some laboratory blood tests of liver (transaminases) or muscle (CK) function, cough, indigestion, heartburn, nausea, joint pain, muscle spasms, neck pain, decreased appetite, pain, chest pain, hot flush, high blood pressure.

- Additionally, when used with a statin, the following side effects were reported:
 - Common: elevations in some laboratory blood tests of liver function (transaminases), headache, muscle pain, tenderness or weakness.
 - Uncommon: tingling sensation, dry mouth, itching, rash, hives, back pain, muscle weakness, pain in arms and legs, unusual tiredness or weakness, swelling, especially in the hands and feet.
 - When used with fenofibrate, the following side effect was reported:
 - Common: abdominal pain.
 - Additionally, the following side effects have been reported in general use: allergic reactions (which may require treatment right

away) including swelling of the face, lips, tongue, and/or throat that may cause difficulty in breathing or swallowing, rash, and hives, raised red rash, sometimes with target-shaped lesions, muscle aches, unusual tiredness or weakness, alterations in some laboratory blood tests, liver problems, inflammation of the pancreas constipation, dizziness, tingling sensation, depression, gallstones, and inflammation of the gallbladder.

- Contact your doctor promptly if you experience unexplained muscle pain, tenderness, or weakness while taking EZEKEM.

- This is because on rare occasions, muscle problems can be serious, including muscle breakdown resulting in kidney damage.

- Talk to your doctor anytime you have a medical problem you think may be related to EZEKEM.

- If you are prescribed EZEKEM with a statin, your healthcare professional may want to conduct routine blood tests to check your liver function before and after starting treatment.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my (Public→ Reporting Medicinal Problems/ Side effects/ AEFI)

Storage and disposal of EZEKEM

Storage

Keep out of the reach and sight of children. Store below 30°C. Protect from moisture.

Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the

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environment.

Product description

White to off white capsule shaped,
flat faced, bevelled edge tablets,
debossed with 'A25' on one side and
plain on other side.

Ingredients

-Active Ingredient

Ezetimibe

-Inactive ingredients

Lactose monohydrate,
Croscarmellose sodium,
Hypromellose, Crospovidone,
Microcrystalline cellulose, Sodium
lauryl sulfate, Magnesium stearate

MAL NO:

xxxxxxxxx

Manufacturer

Alkem Laboratories Limited,
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Product Registration Holder

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