

Mac-Zet (Ezetimibe Tablets USP 10mg)

Ezetimibe (10mg)

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Please read this information carefully before you start to take your medicine, even if you have just refilled your prescription. Some of the information may have changed. You should also read any information provided with other medicines you are currently taking. Remember that your doctor has prescribed this medicine only for you. Never give it to anyone else.

1. WHAT MAC-ZET ARE USED FOR

- Mac-Zet tablets (*ezetimibe*) is a tablet that contains 10 mg of ezetimibe as the active ingredient.
- Mac-Zet tablets is cholesterol-lowering medicine.
- Mac-Zet tablets for patients whose cholesterol levels are too high and when diet alone cannot lower these levels adequately.
- Mac-Zet tablets reduce elevated total-cholesterol, LDL (bad) cholesterol and triglycerides and increases HDL (good) cholesterol.
- Mac-Zet tablets may be taken with other Cholesterol-lowering medicines known as statins or alone, in addition to diet.

- Mac-Zet tablets may be taken with fenofibrate, another cholesterol-lowering medicine, in addition to diet.
- For patients with heart disease, Mac-Zet tablets combined with cholesterol-lowering medicines called statins reduces the risk of heart attack, stroke, surgery to increase heart blood flow, or hospitalization for chest pain.

If you have sitosterolemia, your doctor has prescribed Mac-Zet tablets to lower the level of plant sterols in your blood.

Sitosterolemia is a hereditary illness that increases the levels of plant sterols in your blood.

2. HOW MAC-ZET WORKS:

- Mac-Zet tablets 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.
- Mac-Zet tablets adds to the cholesterol-lowering effect of statins and fenofibrate.

Why has my doctor prescribed Mac-Zet tablets ?

Your doctor has prescribed Mac-Zet tablets 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 Mac-Zet tablets to help lower your cholesterol.

3. BEFORE YOU TAKE MAC-ZET

It is important that you continue taking Mac-Zet tablets 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

Mac-Zet tablets is not recommended in children under age 10

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-When you must not use Mac-Zet

Patients who are hypersensitive (allergic) to Mac-Zet tablets or any of its ingredients should not take Mac-Zet tablets.

-Before you start to take it

Tell your doctor about:

Pregnancy:

If you are pregnant or plan to become pregnant, Mac-Zet tablets may not be right for you.

Breast-feeding:

If you are breast-feeding, Mac-Zet tablets 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 Mac-Zet tablets works
- Fibrates (also used to lower cholesterol)

4. HOW TO USE MAC-ZET:

How much to take

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

When to use Mac-Zet

- Take Mac-Zet tablets with or without food.
- Your doctor may let you take Mac-Zet tablets 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, Mac-Zet tablets can be taken at the same time as the other medicine.
- If your doctor has prescribed Mac-Zet tablets along with cholestyramine (a bile acid sequestrant) or any other bile acid sequestrant, Mac-Zet tablets should be taken at least 2 hours before or 4 hours after taking the bile acid sequestrant.

How long to use Mac-Zet

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

If you forget to use Mac-Zet

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

If you use too much (overdose)

Take Mac-Zet tablet only as prescribed for you. If you take more Mac-Zet tablets than you were prescribed, contact your doctor or pharmacist.

5. WHILE YOU ARE USING MAC-ZET:

- Things you must do

- Mac-Zet tablets 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 Mac-Zet tablets if you are hypersensitive (allergic) to Mac-Zet tablets or any of its ingredients.
- Do not give Mac-Zet tablets to anyone else, even if they have the same symptoms or condition as you.

Things to be careful of

Driving and using machines

There have been side effects reported with Mac-Zet tablets that may affect your ability to drive or operate machinery. Individual responses to Mac-Zet tablets may vary.

6. SIDE EFFECTS

Mac-Zet tablets 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 Mac-Zet tablets.

When used alone, the following side effects were reported:

Common: abdominal pain; diarrhoea; 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.

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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 Mac-Zet tablets.

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 Mac-Zet tablets.

If you are prescribed Mac-Zet tablets 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 nptra.moh.gov.my [Consumers → Reporting → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

7. STORAGE AND DISPOSAL OF MAC-ZET:

- Storage

Store below 30°C. Protect from moisture. Store in the original package. Keep medicine out of reach of children.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

8. PRODUCT DESCRIPTION

What it looks like and contents of the pack

White to off white, capsule shaped, flat bevelled edge, uncoated tablets debossed with "C29" on one side and plain on other side.

Alu/Alu Blister pack of 10 tablets. Available in pack size 3x10's.

- What Mac-Zet contains

Active ingredient:

The active substance is ezetimibe.

Inactive ingredients:

The inactive ingredients are: lactose monohydrate, Croscarmellose sodium, Povidone K-30, Microcrystalline cellulose, sodium lauryl sulfate and Magnesium stearate

- MAL Number:

MALXXXXXXXXXX

9. MANUFACTURER AND PRODUCT REGISTRATION HOLDER

Manufacturer:

Macleods Pharmaceuticals Limited

Block N-2, Village Theda, Post Office Lodhimajra, Tehsil Baddi, District Solan, Himachal Pradesh - 174101, India.

Product Registration Holder:

Macleods Pharmaceuticals Sdn. Bhd.

A2-27-1 Soho Suites KLCC, Jalan Perak, 50450 Kuala Lumpur, Malaysia.

10. Date of revision

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