

ZETEZE-SM

(Ezetimibe/Simvastatin Tablets
10+10 mg, 10+20 mg, 10+40 mg, 10+80 mg)

Consumer Medication Information Leaflet (RiMUP)

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This leaflet answers some common questions about **ZETEZE-SM**.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking **ZETEZE-SM** against the benefits it is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What ZETEZE-SM is used for

ZETEZE-SM contains the active ingredients ezetimibe and simvastatin.

ZETEZE-SM is used to lower levels of total cholesterol, LDL (bad) cholesterol, and fatty substances called triglycerides in the blood. In addition, it raises levels of HDL (good) cholesterol. **ZETEZE-SM** is for patients who cannot control their cholesterol levels by diet alone. You should stay on a cholesterol-lowering diet while taking this medicine.

How ZETEZE-SM works

ZETEZE-SM works to reduce your cholesterol in two ways. The active ingredient ezetimibe reduces the cholesterol absorbed in your digestive tract. The active ingredient simvastatin belonging to the class of "statins"

inhibits the production of the cholesterol your body makes by itself. 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.

Ask your doctor if you have any questions why it has been prescribed for you.

This medicine is only available with a doctor's prescription.

Before you use ZETEZE-SM

When you must not use it

Do not take ZETEZE-SM:

- are hypersensitive (allergic) to ezetimibe, simvastatin, or any of the other ingredients of this medicine (see product description at the end of this leaflet). An allergic reaction may include skin rash, itching, swelling of the face, lips, tongue and throat or difficulty in breathing.
- have active liver disease
- are pregnant or breast-feeding
- are taking any of the following medicines:
 - itraconazole, ketoconazole, posaconazole or voriconazole (used to treat fungal infections)
 - erythromycin, clarithromycin, or telithromycin (used to treat infections)

- HIV protease inhibitors such as nelfinavir (used to treat HIV infections)
- medicines containing cobicistat (used as an enhancer for antiretroviral agents)
- boceprevir or telaprevir (used to treat hepatitis C virus infections)
- nefazodone (used to treat depression)
- gemfibrozil (a fibric acid medicine for lowering cholesterol)
- ciclosporin (used as an immunosuppressant medicine to prevent organ transplant rejection)
- danazol (used in treatment of endometriosis, fibrocystic breast disease and angioedema)

Do not use this medicine after the expiry date printed on the pack has expired or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking ZETEZE-SM, talk to your doctor or pharmacist.

Before you start to use it

Tell your doctor if you have allergies to any other medicines, food, preservatives or dyes.

Tell your doctor:

- about all your medical conditions including allergies.
- if you drink large amounts of alcohol or have ever had liver disease. **ZETEZE-SM** may not be right for you.
- if you are due to have an operation. You may need to stop taking **ZETEZE-SM** for a short time.
- if you are Asian, because a different dose may be applicable to you.

While you are on this medicine your doctor will monitor you closely if you have diabetes or are at risk of developing diabetes. You are likely to be at risk of developing diabetes if you have high levels of sugars and fats in

your blood, are overweight and have high blood pressure.

Tell your doctor if you have severe lung disease.

Also tell your doctor or pharmacist if you have a muscle weakness that is constant. Additional tests and medicines may be needed to diagnose and treat this.

Pregnancy and Lactation

Pregnancy

Do not use **ZETEZE-SM** if you are pregnant, trying to become pregnant or suspect that you are pregnant. If you become pregnant while taking **ZETEZE-SM**, stop taking it and contact your physician immediately.

Lactation

Do not use **ZETEZE-SM** if you are breast-feeding.

If you have not told your doctor about any of the above, tell them before you start taking ZETEZE-SM.

If you are not sure, talk to your doctor or pharmacist before taking ZETEZE-SM.

ZETEZE-SM contains lactose. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Because taking **ZETEZE-SM** with any of the following medicines or substances can increase the risk of muscle problems (see **Side effects**), it is particularly important to tell your doctor if you are taking any of the following medicines or any of the medicines listed in the section “**When you must not use it**”:

- amiodarone (used to treat an irregular heartbeat)
- verapamil, diltiazem, or amlodipine (used to treat high blood pressure,

angina, or other heart conditions)

- grapefruit juice (which should be avoided while taking **ZETEZE-SM**)
- fusidic acid (used to treat bacterial infections)
- colchicine (used for gout)

It is also important to tell your doctor if you are taking anticoagulants (medicines that prevent blood clots, such as warfarin, fluindione), colestyramine (also used to lower cholesterol), rifampicin (used to treat tuberculosis), niacin, or fibrates (fenofibrate including others).

If you have not told your doctor about any of these, tell them before you take **ZETEZE-SM**.

Your doctor or pharmacist has more information on medicines to be careful with or to avoid while taking **ZETEZE-SM**.

How to use ZETEZE-SM

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on this leaflet, ask your doctor or pharmacist for help.

How much to use

Your doctor will determine the appropriate tablet strength for you, depending on your current treatment and your personal risk status.

Always take this medicine exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

- Before starting **ZETEZE-SM**, you should be on a diet to lower your cholesterol.
- You should keep on this cholesterol-lowering diet while taking **ZETEZE-SM**.

The 10/80 mg dose is only recommended for adult patients with very high cholesterol levels and at high risk of heart disease problems who have not reached their cholesterol goal on lower doses.

Children and adolescents

ZETEZE-SM is not recommended in children.

When to use it

Take **ZETEZE-SM** as a single daily dose in the evening, with or without food. Swallow the tablets with a glass of water.

If your doctor has prescribed **ZETEZE-SM** along with a bile acid sequestrant (such as colestyramine), **ZETEZE-SM** should be taken at least 2 hours before or 4 hours after taking the bile acid sequestrant.

How long to use it

ZETEZE-SM helps lower your cholesterol. It does not cure your condition.

Therefore, you must continue to take it as directed by your doctor if you expect to lower your cholesterol and keep it down.

You may have to take cholesterol lowering medicine for the rest of your life. If you stop taking **ZETEZE-SM**, your cholesterol levels may rise again.

If you forget to use it

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

If you are not sure what to do, ask your doctor or pharmacist. **Do not take a double dose to make up for the dose that you missed.**

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you use too much (overdose)

Immediately telephone your doctor for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much of ZETEZE-SM. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Take this leaflet or some tablets with you so your

doctor will know what you have taken.

While you are using ZETEZE-SM

Things you must do

Tell all the doctors, dentists and pharmacists treating you that you are taking ZETEZE-SM.

If you become pregnant while taking ZETEZE-SM, stop taking it and tell your doctor immediately.

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

Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give ZETEZE-SM to anyone else, even if they have the same symptoms or condition as you.

Things to be careful of

Contact your physician promptly if you experience unexplained muscle pain, tenderness, or weakness. This is because on rare occasions, muscle problems can be serious, including muscle breakdown resulting in kidney damage that can lead to death.

The risk of muscle breakdown is also greater in certain patients. Talk with your doctor if any of the following applies:

- older patients (65 years of age and older),
- female patients,
- patients with kidney problems,
- patients with thyroid problems
- you have ever had muscle problems during treatment with cholesterol lowering medicines called “statins” (like simvastatin, atorvastatin, and rosuvastatin) or fibrates (like gemfibrozil and bezafibrate)
- you or close family members have a hereditary muscle disorder.

Dizziness has been reported with ezetimibe and simvastatin. Do not drive or operate machinery until you know how **ZETEZE-SM** affects you.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking ZETEZE-SM.

Like all medicines, **ZETEZE-SM** can have side effects, although not everybody gets them.

Do not be alarmed by the following list of side effects. You may not experience any of them.

Serious side effects

If any of the following happens, stop taking ZETEZE-SM and tell your doctor immediately or go to the casualty/ emergency department at your nearest hospital immediately.

- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- red, often itchy spots, similar to the rash of measles, which may blister or may progress to form raised, red, pale-centred marks.
- if you have muscle problems that do not go away even after your doctor has told you to stop taking **ZETEZE-SM**, please refer to your doctor. Your doctor may do further tests to diagnose the cause of your muscle problems.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- temporary paralysis or weakness of muscles with or without kidney failure
- aching muscles, muscle tenderness or weakness, not caused by exercise
- Joint pain; muscle pain or spasms; muscular weakness; musculoskeletal discomfort; neck pain; back pain, pain in extremity
- tendon problems, sometimes complicated by rupture of the tendon
- bleeding or bruising more easily than normal bleeding or bruising

- more easily than normal
- tiredness, headaches, being short of breath when exercising, dizziness and looking pale
- severe upper stomach pain, often with nausea and vomiting, inflammation of the stomach
- breathing problems including persistent cough and/or shortness of breath or fever

If you are prescribed **ZETEZE-SM**, your doctor may want to conduct routine blood tests to check your liver function before and after starting treatment and if you have any symptoms of liver problems while you take **ZETEZE-SM**. Call your doctor right away if you have the following symptoms of liver problems:

- feel tired or weak
- loss of appetite
- upper belly pain
- dark urine
- yellowing of your skin or the whites of your eyes

Other side effects

Tell your doctor if you notice any of the following:

- numbness or weakness of the arms and legs
- memory impairment, memory loss, forgetfulness, confusion

Laboratory Abnormalities

- increase in liver enzymes, bilirubin, blood uric acid, blood creatine kinase
- increase in international normalised ratio
- increase in blood sugar levels
- presence of protein in urine
- abnormal blood cell counts

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

Ask your doctor or pharmacist to answer any questions you may have.

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 [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of ZETEZE-SM

Storage

Store below 30°C.

Disposal

Return any unused or expired medicine to your doctor, pharmacist or health care professional for safe disposal.

Product Description

What it looks like**ZETEZE-SM 10+10 mg**

Ezetimibe and Simvastatin 10/10 mg tablets are White to off-white, capsule shaped uncoated tablets, debossed with 'L' on one side and plain on other side.

ZETEZE-SM 10+20 mg

Ezetimibe and Simvastatin 10/20 mg tablets are White to off-white, capsule shaped uncoated tablets, debossed with 'I' on one side and plain on other side

ZETEZE-SM 10+40 mg

Ezetimibe and Simvastatin 10/40 mg tablets are White to off-white, capsule shaped uncoated tablets, debossed with 'F' on one side and plain on other side.

ZETEZE-SM 10+80 mg

Ezetimibe and Simvastatin 10/80 mg tablets are White to off-white, capsule shaped uncoated tablets, debossed with 'T' on one side and plain on other side.

Ingredients**Active ingredients:**

Ezetimibe and Simvastatin Tablets

Inactive ingredients:

Lactose Monohydrate, Croscarmellose Sodium, Hypromellose, Cellulose Microcrystalline, Citric Acid Monohydrate, Propyl Gallate, Butylated Hydroxy Anisole, Magnesium Stearate.

MAL Number:

ZETEZE-SM 10+10 mg
(MAL19056026AZ)

ZETEZE-SM 10+20 mg
(MAL19056027AZ)

ZETEZE-SM 10+40 mg
(MAL19056028AZ)

ZETEZE-SM 10+80 mg
(MAL19056029AZ)

Manufacturer and Product Registration Holder

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Product Registration Holder

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