

NEW ZEALAND CONSUMER MEDICINE INFORMATION

ZIMYBE® 10/10, 10/20, 10/40 & 10/80

Ezetimibe/Simvastatin Tablets

10mg/10mg, 10mg/20mg, 10mg/40mg & 10mg/80mg



What is in this leaflet

Please read this leaflet carefully before you start taking ZIMYBE.

This leaflet answers some common questions about ZIMYBE.

It does not contain all 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 ZIMYBE against the benefits they expect it will 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 ZIMYBE is used for

ZIMYBE helps to lower cholesterol and triglyceride levels. It is used in people whose cholesterol levels are too high and when diet alone cannot lower these levels adequately.

ZIMYBE contains the active ingredients ezetimibe and simvastatin.

It works by reducing elevated total cholesterol, LDL cholesterol and triglycerides, and increasing HDL cholesterol.

ZIMYBE works by decreasing the absorption of cholesterol in the small intestine and by reducing the amount of cholesterol made in the

liver. ZIMYBE does not help you to lose weight.

Your doctor may have prescribed it for another reason.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

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

This medicine is not addictive.

ZIMYBE is not recommended for use in children under 10 years of age.

Cholesterol

Cholesterol is one of several fatty substances found in the bloodstream. Your total cholesterol is made up mainly of low-density lipoprotein (LDL) and high-density lipoprotein (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 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

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

Before you take ZIMYBE

When you must not take it

Do not take ZIMYBE if you have an allergy to:

- any medicine containing ezetimibe or simvastatin
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take this medicine if you are pregnant.

It may affect your developing baby if you take it during pregnancy.

Do not breast-feed if you are taking this medicine.

The active ingredients in ZIMYBE may pass into breast milk and there is a possibility that your baby may be affected.

Do not take this medicine if you have active liver disease or repeated blood tests indicating possible liver problems.

Do not take this medicine if you have had muscle pain, tenderness or weakness from other medicines used to treat high cholesterol or triglycerides.

Do not take this medicine if you are taking any of the following:

- ketoconazole, itraconazole, posaconazole and

voriconazole used to treat certain fungal infections

- erythromycin, clarithromycin, telithromycin and fusidic acid; antibiotics used to treat infections
- HIV protease inhibitors, used to treat HIV infection, including indinavir, nelfinavir, ritonavir, saquinavir
- boceprevir or telaprevir, used to treat Hepatitis C virus infections
- medicines containing cobicistat, used in the treatment of HIV infection
- nefazodone, a medicine used to treat depression
- danazol, a hormone used to treat gynaecological problems
- cyclosporin, a medicine used to suppress the immune system
- gemfibrozil, a medicine used to lower cholesterol levels

Do not take this medicine after the expiry date printed on the pack 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 this medicine, talk to your doctor.

Before you start to take it

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

Tell your doctor if you have or have had any of the following medical conditions:

- an underactive thyroid gland
- high blood pressure
- high body mass
- liver disease or liver problems,
- kidney disease or any other kidney problems

Tell your doctor if you drink alcohol regularly.

Tell your doctor if you plan to become pregnant or plan to breast-feed.

Your doctor can discuss with you the risks and benefits involved.

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

Taking other medicines

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

You should also tell any health professional who is prescribing a new medication for you that you are taking ZIMYBE.

Some medicines may interfere with ZIMYBE. These include:

- medicines used to lower cholesterol levels, such as bile acid sequestrants, e.g. colestyramine, other fibrates or nicotinic acid (also known as niacin).
- elbasvir or grazoprevir used to treat Hepatitis C virus infections.
- amiodarone, a medicine used to treat irregular heartbeat
- amlodipine, diltiazem or verapamil, medicines used to treat high blood pressure and angina
- colchicine, a medicine used for gout
- lomitapide, a medicine used to treat a serious and rare genetic cholesterol condition
- warfarin, fluindione or other medicines used to prevent blood clots
- antacids, medicines which neutralize stomach acidity and are used to relieve heartburn, indigestion or an upset stomach
- digoxin, a medicine used to treat various heart conditions
- ticagrelor, a medicine used in combination with aspirin to prevent heart attack.

These medicines may be affected by ZIMYBE or may affect how well it works. You may need different

amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take ZIMYBE

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 the box, ask your doctor or pharmacist for help.

How much to take

The recommended dose is one ZIMYBE 10/10, 10/20, 10/40 or 10/80 tablet once a day, in the evening.

The 10/80 mg dose of ZIMYBE is only recommended for patients at high risk of heart disease problems who have not yet reached their cholesterol goal on lower doses and when the benefits outweigh the risk.

How to take it

Swallow the tablets whole with a full glass of water.

Grapefruit juice should be avoided while taking ZIMYBE. Grapefruit juice contains one or more components that alter the metabolism of some medicines, including ZIMYBE.

When to take it

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take this medicine before or after food.

If you are taking a bile acid sequestrant, such as colestyramine, take ZIMYBE either at least two hours before

or four hours after taking the bile acid sequestrant.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

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

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

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

While you are taking ZIMYBE

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking ZIMYBE.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked. Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

Do not take ZIMYBE to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Things to be careful of

Avoid drinking large quantities of alcohol.

Drinking large quantities of alcohol may increase your chance of ZIMYBE causing liver problems.

Be careful driving or operating machinery until you know how ZIMYBE affects you.

There have been side effects reported with ZIMYBE that may affect your ability to drive or operate machinery.

High cholesterol can be treated in two main ways

Lifestyle changes: This includes a cholesterol-lowering diet, increasing physical activity, and weight management. Ask your doctor for

advice before increasing physical activity.

Medicines: Cholesterol-lowering medicines are used together with lifestyle changes to help lower cholesterol.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Information Centre (telephone 0800 POISON or 0800 764 766), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much ZIMYBE. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Side effects

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

This medicine helps most people with high cholesterol but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- dizziness
- confusion
- poor memory
- depression
- nausea or vomiting
- stomach pain or discomfort
- indigestion
- excessive gas in the stomach or bowel

- diarrhoea
- constipation
- tingling or numbness of the hands or feet
- trouble sleeping
- erectile dysfunction
- hot flush
- weight loss
- dry mouth
- heartburn
- coughing
- high blood pressure
- unusual hair loss.

Tell your doctor as soon as possible if you notice any of the following:

- unexplained muscle aches, muscle tenderness or weakness, not caused by exercise (in some cases this may not go away after stopping ZIMYBE)
- muscle cramps or spasms
- numbness or weakness of the arms and legs
- muscle rupture
- tiredness
- headache
- being short of breath when exercising, dizziness and looking pale
- fever, generally feeling unwell
- bleeding or bruising more easily than normal
- breathing problems including persistent cough and/or shortness of breath
- steady abdominal pain with nausea and vomiting
- vomiting blood
- blood in the bowel motions
- pain - back, neck, joint or muscle pain
- skin rash, itchiness or itchy swellings on the skin
- swelling of hands, ankles or feet
- blurred vision and impaired vision
- gynaecomastia (breast enlargement in men)
- rash that occurs on the skin or sores in the mouth (lichenoid drug eruptions).

The above list includes serious side effects that may require medical attention.

Muscle problems can be serious including muscle breakdown

resulting in kidney damage that can lead to death. You may need urgent medical attention.

The risk of muscle breakdown is greater for patients taking higher doses of ZIMYBE.

The risk of muscle breakdown is also great for older patients (65 years of age and older), female patients, patients with abnormal kidney function and patients with thyroid problems.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- swelling of the face, lips, mouth, throat or tongue which may cause difficulty in swallowing or breathing
- chest pain
- signs of liver problem such as nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, and dark coloured urine.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

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

Some side effects such as changes to liver function can only be found when your doctor does tests from time to time to check your progress.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After taking ZIMYBE

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store ZIMYBE or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

ZIMYBE comes in four types of tablets:

- ZIMYBE 10/10 – 10mg ezetimibe / 10mg simvastatin. White to off-white, oval, biconvex tablet marked with M on one side and ES1 on the other side
- ZIMYBE 10/20 – 10mg ezetimibe / 20mg simvastatin. White to off-white, oval, biconvex tablet marked with M on one side and ES2 on the other side
- ZIMYBE 10/40 – 10mg ezetimibe / 40mg simvastatin. White to off-white, oval, biconvex tablet marked with M on one side and ES3 on the other side
- ZIMYBE 10/80 – 10mg ezetimibe / 80mg simvastatin. White to off-white, oval, biconvex tablet marked with M on one side and ES4 on the other side.

Ingredients

Active ingredients:

ZIMYBE tablets contain ezetimibe and simvastatin as the active ingredients.

Inactive ingredients:

ZIMYBE tablets also contain:

- lactose monohydrate
- citric acid monohydrate
- butylated hydroxyl anisole
- ascorbic acid
- croscarmellose sodium
- hypromellose
- sodium lauryl sulphate
- microcrystalline cellulose
- magnesium stearate.

Sulfites may be present in ZIMYBE tablets in trace amounts.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

ZIMYBE is supplied in New Zealand by:

Viatris Ltd
PO Box 11-183
Ellerslie
AUCKLAND
www.viatris.co.nz
Telephone: 0800 168 169

Date of Preparation

16 January 2023
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ZIMYBE® is a Viatris company trade mark.