

ZIMYBE®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using ZIMYBE?

ZIMYBE contains the active ingredients ezetimibe and simvastatin. ZIMYBE is used 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.

For more information, see Section [1. Why am I using ZIMYBE?](#) in the full CMI.

2. What should I know before I use ZIMYBE?

Do not use if you have ever had an allergic reaction to ezetimibe and simvastatin or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use ZIMYBE?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ZIMYBE and affect how it works. Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ZIMYBE.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use ZIMYBE?

- The recommended dose in adults (18 years and over) is one ZIMYBE 10/10, 10/20, 10/40 or 10/80 tablet once a day, in the evening.
- The recommended dose in adolescents (10 to 17 years of age) with familial hypercholesterolaemia is one ZIMYBE 10/10, 10/20 or 10/40 tablet once a day, in the evening. The maximum recommended dose in adolescents is 10/40 mg.

More instructions can be found in Section [4. How do I use ZIMYBE?](#) in the full CMI.

5. What should I know while using ZIMYBE?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist
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	<p>you visit that you are using ZIMYBE.</p> <ul style="list-style-type: none"> • Have your blood fats checked when your doctor says, to make sure ZIMYBE is working.
Things you should not do	<ul style="list-style-type: none"> • 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 change the dosage without checking with your doctor.
Driving or using machines	<ul style="list-style-type: none"> • Be careful before you drive or use any machines or tools until you know how ZIMYBE affects you. Side effects reported with ZIMYBE may affect your ability to drive or operate heavy machinery
Drinking alcohol	<ul style="list-style-type: none"> • Avoid drinking large quantities of alcohol. Drinking large quantities

	of alcohol may increase your chances of ZIMYBE causing liver problems.
Looking after your medicine	<ul style="list-style-type: none"> • 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.

For more information, see Section [5. What should I know while using ZIMYBE?](#) in the full CMI.

6. Are there any side effects?

Seek immediate medical attention if you experience any difficulty in breathing or swallowing, swelling of the face, lips, mouth, throat or tongue and unexplained muscle aches, tenderness or weakness not caused by exercise.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

ZIMYBE®

Active ingredient(s): *ezetimibe and simvastatin*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ZIMYBE. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ZIMYBE.**

Where to find information in this leaflet:

- [1. Why am I using ZIMYBE?](#)
- [2. What should I know before I use ZIMYBE?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use ZIMYBE?](#)
- [5. What should I know while using ZIMYBE?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using ZIMYBE?

ZIMYBE contains the active ingredients ezetimibe and simvastatin.

ZIMYBE is used 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.

Cholesterol

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 the arteries forming plaque.

This narrowing can slow or block blood flow to vital organs such as the heart or the 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.

ZIMYBE reduces elevated total cholesterol, LDL (bad) cholesterol and triglycerides and increases HDL

(good) cholesterol.

ZIMYBE also works by decreasing the absorption of cholesterol in the small intestines and by reducing the amount of cholesterol made in the liver. ZIMYBE does not help you lose weight.

If you have heart disease and a history of heart attack or hospitalisation for unstable angina (chest pain), ZIMYBE reduces the risk of heart attack, stroke, surgery to increase heart blood flow, or hospitalisation for chest pain.

Your doctor may have prescribed it for another reason.

ZIMYBE is not addictive.

ZIMYBE is available from pharmacies only with a doctor's prescription.

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

Use in Children and Adolescents

ZIMYBE is used in children and adolescents (10 to 17 years of age) to treat familial hypercholesterolaemia, a type of high cholesterol that is hereditary (i.e. passed on through families).

ZIMYBE is not recommended for use in children under 10 years of age as there have been no studies on its effects in this age group. Your doctor will assess whether

ZIMYBE is suitable for your child. Depending on the pubertal development of your child, ZIMYBE may not be suitable for him or her.

2. What should I know before I use ZIMYBE?

Warnings

Do not use ZIMYBE if:

- you are allergic to simvastatin or ezetimibe, or 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
- Always check the ingredients to make sure you can use this medicine.
- you are pregnant.
- you are breastfeeding.
- you have active liver disease or repeated blood tests indicating possible liver problems.
- you have had muscle pain, tenderness or weakness from other medicines used to treat high cholesterol or triglycerides.
- you are taking certain medicines such as gemfibrozil, ciclosporin, danazol, fusidic acid hemihydrate and strong CYP3A4 inhibitors like itraconazole and ketoconazole. Please see the section "What if I

am taking other medicines?" in this CMI for more information.

- the packaging is torn or shows signs of tampering or after the expiry date printed on the pack. If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking ZIMYBE, talk to your doctor.

Check with your doctor if you:

- have allergies to any other medicines, foods, preservatives, or dyes.
- you have unexplained muscle pain, tenderness or weakness not caused by exercise. This is because on the rare occasion, muscle problems can be serious, including muscle breakdown resulting in kidney damage that can lead to death. Your doctor may do a blood test to check for certain muscle problems.
- you are Asian
- you are taking niacin or a niacin-containing product.
- you have, or have had any medical conditions, including liver disease or liver problems. Your doctor will do a blood test to make sure you have no problems with your liver.
- you have kidney disease or any other medical problems.
- you drink alcohol regularly.
- take any medicines for any other condition.

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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Do not take this medicine if you are pregnant. It may affect your developing baby if you take it during pregnancy. ZIMYBE is contraindicated (i.e. should not be used) during pregnancy and breastfeeding. If you take this medicine during pregnancy and breastfeeding, your baby may absorb this medicine and it may affect your baby's normal development causing birth defects or irreversible damage.

3. What if I am taking other medicines?

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

Some medicines should not be taken with ZIMYBE. These

include:

- nefazodone, used to treat depression

- medicines containing cobicistat, a drug used in the treatment of HIV infection.
- protease inhibitors, used to treat HIV infection, including indinavir, nelfinavir, ritonavir, saquinavir
- certain protease inhibitors, used to treat Hepatitis C virus infection, such as boceprevir or telaprevir
- gemfibrozil, used to treat high cholesterol levels
- ciclosporin, used to suppress the immune system
- danazol
- erythromycin, clarithromycin, telithromycin and fusidic acid hemihydrate, antibiotics used to treat infections
- ketoconazole, itraconazole, posaconazole and voriconazole used to treat certain fungal infections.

If you are taking any of the above, your doctor may suggest stopping ZIMYBE temporarily or permanently.

Some medicines may interfere with ZIMYBE and affect how it works. These include:

- Certain hepatitis C antiviral agents, such as elbasvir, or grazoprevir
- bile acid sequestrants such as colestyramine, used to lower cholesterol levels
- other medicines to lower cholesterol levels for example, other fibrates, nicotinic acid (also known as niacin)
- warfarin, fluindione, or other drugs used to prevent blood clots
- colchicine, used for gout
- verapamil, used to treat high blood pressure and angina

- diltiazem, used to treat angina
- amiodarone, used to treat irregular heart beat
- amlodipine, used to treat high blood pressure and angina
- digoxin, used to treat heart failure.
- lomitapide (a drug used to treat a serious and rare genetic cholesterol condition)
- daptomycin, a drug used to treat complicated skin and skin structure infections and bacteraemia

These medicines may be affected by ZIMYBE, may affect how well it works or may increase the risk of side effects with ZIMYBE. You may need different amounts of your medicines, or you may need to take different medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ZIMYBE.

4. How do I use ZIMYBE?

How much to take

- Take ZIMYBE only when prescribed by your doctor.
- The recommended dose in adults (18 years and over) is one ZIMYBE 10/10, 10/20, 10/40 or 10/80 tablet once a day, in the evening. Your doctor will adjust your ZIMYBE dose depending on your response.
- Because of the increased risk of muscle problems, the ZIMYBE 10/80 tablet is only for patients at high risk

of heart disease problems who have not yet reached their cholesterol goal on lower doses.

- The recommended dose in adolescents (10 to 17 years of age) with familial hypercholesterolaemia is one ZIMYBE 10/10, 10/20 or 10/40 tablet once a day, in the evening. The maximum recommended dose in adolescents is 10/40 mg.
- Follow the instructions provided and use ZIMYBE until your doctor tells you to stop.

When to take ZIMYBE

- ZIMYBE should be taken once a day in the evening. The liver produces its greatest amount of cholesterol when the body is at rest and when there is no dietary intake. For most people this is at night when asleep. Therefore, ZIMYBE is more effective when taken in the evening.

A good time would be after your evening meal. It does not matter if you take it before or after food.

- 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 your dose.
- Your doctor may ask you to take ZIMYBE with other cholesterol lowering agents such as bile acid sequestrants.
- If you are taking a bile acid sequestrant, such as colestyramine, take your ZIMYBE either at least two hours before or four hours after taking the bile acid sequestrant.

How long to take ZIMYBE for

- ZIMYBE helps lower your cholesterol. It does not cure your condition. It is important to keep taking your medicine even if you feel well.
- Continue taking ZIMYBE 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 ZIMYBE, your cholesterol levels may rise again.

How to take ZIMYBE

- Swallow ZIMYBE tablets whole with a full glass of water.

If you forget to take ZIMYBE

ZIMYBE should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember, and then go back to taking your medicines as you would normally.

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

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

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

- If you are not sure what to do or whether to skip the dose, ask your doctor or pharmacist.

If you use too much ZIMYBE

If you think that you have used too much ZIMYBE, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using ZIMYBE?

Things you should do

Have your blood fats checked when your doctor says, to make sure ZIMYBE is working.

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

Call your doctor straight away if you:

- Are about to be started on any new medicines
- Are going to have surgery. Tell the surgeon or anesthetist that you are taking this medicine. It may affect other medicines used during surgery. Your doctor may suggest stopping the tablets a few days before surgery.
- Become pregnant while taking this medicine.

Remind any doctor, dentist or pharmacist you visit that you are using ZIMYBE.

Things you should 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 change the dosage without checking with your doctor.

Lifestyle measures that help reduce heart disease risk

By following these simple measures, you can further reduce the risk from heart disease.

- Quit smoking and avoid secondhand smoke.
- Limit alcohol intake.
- Enjoy healthy eating by:
 - eating plenty of vegetables and fruit;

- reducing your saturated fat intake (eat less fatty meats, full fat dairy products, butter, coconut and palm oils, most take-away foods, commercially-baked products).
- Be active. Progress, over time, to at least 30 minutes of moderate intensity physical activity on 5 or more days each week. Can be accumulated in shorter bouts of 10 minutes duration. If you have been prescribed anti-angina medicine, carry it with you when being physically active.
- Maintain a healthy weight.
- Discuss your lifestyle and lifestyle plans with your doctor.
- For more information and tools to improve your heart health, call Heartline, the Heart Foundation's national telephone information service, on 1300 36 27 87 (local call cost).

Know warning signs of heart attack and what to do:

- Tightness, fullness, pressure, squeezing, heaviness or pain in your chest, neck, jaw, throat, shoulders, arms or back.
- You may also have difficulty breathing, or have a cold sweat or feel dizzy or light headed or feel like vomiting (or actually vomit).
- If you have heart attack warning signs that are severe, get worse or last for 10 minutes even if they are mild, call triple zero (000). Every minute counts.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how ZIMYBE affects you.

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

Grapefruit juice

Grapefruit juice should be avoided while taking ZIMYBE.

Grapefruit juice contains one or more components that alter the metabolism of some medicines, including ZIMYBE.

Drinking alcohol

Avoid drinking large quantities of alcohol.

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

Looking after your medicine

- 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.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

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

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects. Tell your doctor or pharmacist as

soon as possible if you do not feel well while you are taking ZIMYBE.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> ● headache ● nausea ● muscle aches ● dizziness ● cough ● feeling tired ● stomach irritation ● diarrhoea ● decreased appetite ● hot flush ● hypertension (high blood pressure) ● pain 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you. These are the more common side effects of ZIMYBE or of either ezetimibe or simvastatin.</p>
<ul style="list-style-type: none"> ● depression ● tingling or numbness of the hands or feet ● trouble sleeping ● poor memory ● confusion ● erectile dysfunction ● breathing problems including persistent cough and/or shortness of breath or fever. 	<p>Tell your doctor if you notice any of the following.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> ● Swelling of the face, lips, mouth, throat or tongue which may cause difficulty in swallowing or breathing 	<p>Call your doctor immediately or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects. If you have them, you may have had a serious reaction to ZIMYBE. You may require urgent medical attention or hospitalisation.</p>
<ul style="list-style-type: none"> ● skin rash and hives ● raised red rash, sometimes with targeted-shaped lesions ● dark coloured urine ● light coloured bowel motions ● joint pain ● bleeding or bruising more easily than normal 	<p>Tell your doctor immediately if you notice any of the following. These are serious side effects that may require medical attention.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> ● steady abdominal pain with nausea and vomiting. 	
<ul style="list-style-type: none"> ● feel tired or weak ● loss of appetite ● upper belly pain ● dark urine ● yellowing of the skin or the white of your eyes. 	<p>Tell your doctor immediately if you notice any of the following symptoms of liver problems.</p>
<ul style="list-style-type: none"> ● unexplained muscle aches, tenderness or weakness not caused by exercise. <p>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 greater at higher doses of ZIMYBE particularly the 10/80 mg dose. The risk of muscle breakdown is also greater for older patients (65 years of age or older), female patients, patients with kidney problems</p>	<p>Tell your doctor immediately if you notice any of the following. These are serious side effects that may require urgent medical attention. Serious side effects are rare.</p>

Serious side effects	What to do
and patients with thyroid problems.	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

In adolescent patients (10 to 17 years of age) there have been no studies longer than 1 year of the effect of taking ZIMYBE on bone development, growth, social and emotional development, or fertility.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What ZIMYBE contains

Active ingredient (main ingredient)	ZIMYBE 10/10 - 10 mg ezetimibe and 10 mg simvastatin. ZIMYBE 10/20 - 10 mg ezetimibe and 20 mg simvastatin. ZIMYBE 10/40 - 10 mg ezetimibe and 40 mg simvastatin ZIMYBE 10/80 - 10 mg ezetimibe and 80 mg simvastatin.
Other ingredients (inactive ingredients)	Butylated hydroxyanisole Citric acid monohydrate Ascorbic acid Croscarmellose sodium Hypromellose Lactose Sodium lauryl sulphate Magnesium stearate Microcrystalline cellulose

Potential allergens	<p>ZIMYBE 10/10 contains lactose.</p> <p>ZIMYBE 10/20, ZIMYBE 10/40 &</p> <p>ZIMYBE 10/80: Contains sugars (as lactose).</p>
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Do not take this medicine if you are allergic to any of these ingredients.

ZIMYBE does not contain, sucrose, gluten, tartrazine or any other azo dyes.

What ZIMYBE looks like

ZIMYBE tablets are available in 4 different strengths:

ZIMYBE 10/10 - 10mg ezetimibe/10mg simvastatin: A white to off-white, oval, biconvex tablet debossed with M on one side of the tablet and ES1 on the other side. Blister packs of 30. (AUST R 206627)

ZIMYBE 10/20 - 10mg ezetimibe/20mg simvastatin: A white to off-white, oval, biconvex tablet debossed with M on one side of the tablet and ES2 on the other side. Blister packs of 30. (AUST R 206629)

ZIMYBE 10/40 - 10mg ezetimibe/40mg simvastatin: A white to off-white, oval, biconvex tablet debossed with M on one side of the tablet and ES3 on the other side. Blister packs of 30. (AUST R 206631)

ZIMYBE 10/80 - 10mg ezetimibe/ 80mg simvastatin: A white to off-white, oval, biconvex tablet debossed with M on one side of the tablet and ES4 on the other side. Blister packs of 30. (AUST R 206628)

Who distributes ZIMYBE

Alphapharm Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.mylan.com.au

ZIMYBE® is a Viartis company trade mark

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