

ZIMSTAT

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 taking ZIMSTAT?

ZIMSTAT contains the active ingredient simvastatin. ZIMSTAT is used to lower cholesterol and triglyceride levels.

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

2. What should I know before I take ZIMSTAT?

Do not take if you have ever had an allergic reaction to 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 take ZIMSTAT?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ZIMSTAT and affect how it works.

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

4. How do I take ZIMSTAT?

- For adults, the recommended starting dose is 10 mg or 20 mg in the evening. Your doctor may increase this dose up to 80 mg daily to manage the disease most effectively.
- People with cardiovascular heart disease (CHD) or risk factors for CHD are usually started on 40 mg in the evening.
- For children (10-17 years old), the recommended usual starting dose is 10 mg a day in the evening. The maximum recommended dose is 40 mg a day.

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

5. What should I know while taking ZIMSTAT?

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| Things you should do | <ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are taking ZIMSTAT. |
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| | <ul style="list-style-type: none"> • If you become pregnant while you are taking ZIMSTAT, stop taking the medicine and contact your doctor immediately. • Have your blood fats checked when your doctor says, to make sure ZIMSTAT is working. |
| <p>Things you should not do</p> | <ul style="list-style-type: none"> • Do not stop taking ZIMSTAT, or lower the dose without checking with your doctor. • Grapefruit juice should be avoided while taking ZIMSTAT. |
| <p>Driving or using machines</p> | <ul style="list-style-type: none"> • Be careful driving or operating machinery until you know how ZIMSTAT affects you. • ZIMSTAT may cause dizziness in some people. Make sure you know how you react to ZIMSTAT before you drive a car or operate machinery. |

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| <p>Drinking alcohol</p> | <ul style="list-style-type: none"> ● Avoid drinking large quantities of alcohol. ● Drinking large quantities of alcohol may increase your chance of ZIMSTAT causing liver problems. |
| <p>Looking after your medicine</p> | <ul style="list-style-type: none"> ● Keep ZIMSTAT where children cannot reach it. ● 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 taking ZIMSTAT?](#) in the full CMI.

6. Are there any side effects?

Tell your doctor or pharmacist if you notice any of these common side effects and they worry you: constipation, diarrhoea, wind, stomach upset, feeling sick, headache and dizziness. Tell your doctor immediately if you notice any aching muscles, muscle tenderness or weakness not caused by exercise, brown/black urine, feeling tired or weak, loss of appetite, upper belly pain, dark urine and yellowing of your skin or the whites of your eyes. Tell your doctor immediately or go to emergency department if you have swelling of the face, mouth, difficulty in swallowing, shortness of breath, double vision or drooping eyelids.

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.

ZIMSTAT

Active ingredient: *simvastatin*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ZIMSTAT. **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 ZIMSTAT.**

Where to find information in this leaflet:

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

1. Why am I taking ZIMSTAT?

ZIMSTAT contains the active ingredient simvastatin. ZIMSTAT helps to lower cholesterol and triglyceride levels.

ZIMSTAT is used in people who have coronary heart disease (CHD) or who are at high risk of CHD (for example, if they have diabetes, a history of stroke, or other blood vessel disease).

Zimstat may be used in these people, regardless of their cholesterol level to:

- help prolong life by reducing the risk of a heart attack
- reduce the risk of stroke
- reduce the need for surgery to increase blood flow to the heart
- reduce the need for hospitalisation due to angina.

ZIMSTAT is used in boys and girls (10 to 17 years of age), who had started their menstrual period at least one year before, to treat familial hypercholesterolaemia, a type of high cholesterol that is hereditary (i.e., passed on through families).

Cholesterol

Everyone has cholesterol and triglycerides in their blood. They are types of blood fat needed by the body for many things, including building cell walls, making bile acids (which help to digest food) and certain hormones. However, too much cholesterol can be a problem.

Your body makes cholesterol, but it also comes from food.

Normally the body balances the cholesterol it makes with the cholesterol it gets from food. This means if more cholesterol comes from food, less is made by the body.

However, if you eat a diet high in fat, your body may not keep this balance and your cholesterol levels rise.

High cholesterol is more likely to occur with certain diseases or if you have a family history of high cholesterol.

When you have high levels of cholesterol, it may 'stick' to the inside of your blood vessels instead of being carried to the parts of the body where it is needed. Over time, this can form hard areas, called plaque, on the walls of blood vessels, making it more difficult for the blood to flow. This blocking of your blood vessels can lead to coronary heart disease (such as heart attack and angina), and stroke.

In people with coronary heart disease (CHD), ZIMSTAT may slow down the hardening of blood vessels and reduce the risk of developing new plaques.

There are different types of cholesterol, called LDL and HDL cholesterol. LDL cholesterol is the 'bad' cholesterol that can block your blood vessels. HDL cholesterol, on the other hand, is the 'good' cholesterol that is thought to remove the 'bad' cholesterol from the blood vessels.

Triglycerides

Triglycerides are an energy source for the body. However, as with cholesterol, too much triglycerides can be a problem.

How ZIMSTAT works

ZIMSTAT belongs to a group of medicines known as HMG-CoA reductase inhibitors (also known as "statins"). It works by reducing the amount of cholesterol made by the liver. In terms of good and bad cholesterol, ZIMSTAT reduces the bad cholesterol and raises the good cholesterol.

ZIMSTAT does not reduce the cholesterol and triglycerides that come from fat in food.

Therefore, when you are taking ZIMSTAT you also need to follow a low fat diet and other measures, such as exercise and weight control.

In most people, there are no symptoms of high cholesterol or triglycerides. Your doctor can measure your cholesterol and triglycerides with a simple blood test.

Your doctor may have prescribed ZIMSTAT for another reason. Ask your doctor if you have any questions about why ZIMSTAT has been prescribed for you.

ZIMSTAT is not addictive.

2. What should I know before I take ZIMSTAT?

Warnings

Do not use ZIMSTAT if:

- **you are allergic to simvastatin, or any of the ingredients listed at the end of this leaflet.**
Symptoms of an allergic reaction may include skin rash, itchiness, shortness of breath, swelling of the tongue or face, or painful joints
- Always check the ingredients to make sure you can use this medicine.
- **you have liver disease**
- **you have had muscle pain, tenderness or weakness from other medicines used to treat high cholesterol or triglycerides**
- **the packaging is torn or shows signs of tampering or after the expiry date printed on the pack. If it has expired or the package is damaged, return it to your pharmacist for disposal.**

Check with your doctor if you:

- **you have unexplained muscle pain, tenderness or weakness not caused by exercise. This is because on rare occasions, 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 taking niacin or a niacin-containing product, particularly if you are Asian.**
- **you have ever had liver disease**
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**
- **you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.**
- **you have or have had myasthenia gravis (a disease-causing general muscle weakness including in some cases muscles used for breathing) or ocular myasthenia (a disease causing eye muscle weakness) as statins may lead to occurrence of myasthenia or aggravate the condition.**

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.

Your baby may absorb this medicine in the womb or from breast milk and therefore there is a possibility of harm to the baby.

ZIMSTAT should not be used during pregnancy or while breastfeeding.

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 ZIMSTAT as they may increase the risk of muscle side effects with ZIMSTAT. It is particularly important to tell your doctor if you are taking:

- 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 hepatitis C virus protease inhibitors (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 ZIMSTAT temporarily or permanently.

Some medicines and ZIMSTAT may interfere with each other. Because taking ZIMSTAT with any of the following drugs can increase the risk of muscle problems (see Are there any side effects?), it is particularly important to tell your doctor if you are taking:

- other medicines to lower cholesterol levels, for example, other fibrates (such as gemfibrozil) and nicotinic acid (also known as niacin)
- warfarin, ticagrelor or other drugs used to prevent blood clots
- colchicine, used for gout
- verapamil, diltiazem or amlodipine, used to treat high blood pressure, angina or other heart conditions
- lomitapide (a drug used to treat a serious and rare genetic cholesterol condition)
- amiodarone, used to treat irregular heart beat
- digoxin, used to treat heart failure
- certain hepatitis C antiviral agents, such as elbasvir or grazoprevir
- daptomycin, a drug used to treat complicated skin and skin structure infections and bacteraemia

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

You should tell your doctor who is prescribing a new medication for you that you are taking ZIMSTAT.

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

4. How do I take ZIMSTAT?

How much to take

- **Take ZIMSTAT only when prescribed by your doctor.**
- Your doctor will tell you how many tablets you need to
- take each day. This depends on your cholesterol and
- triglyceride levels and other factors, such as kidney
- disease.
- For adults, the recommended starting dose is 10 mg or 20
- mg per day, taken in the evening. Your doctor may
- increase this dose up to 80 mg daily to manage the disease

- most effectively.
- Because of the increased risk of muscle problems, the 80 mg dose is only for patients at high risk of heart disease
- problems who have not reached their cholesterol goal on lower doses.
- People with cardiovascular heart disease (CHD) or risk factors for CHD are usually started on 40 mg per day, taken in the evening.
- For children (10-17 years old), the recommended usual starting dose is 10 mg a day in the evening. The maximum recommended dose is 40 mg a day.

How to take ZIMSTAT

- Swallow the tablets with a glass of water.

When to take ZIMSTAT

Take ZIMSTAT 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, ZIMSTAT is more effective when taken in the evening. A good time would be after your evening meal.

However, it does not matter whether you take it before or after food.

Take ZIMSTAT at about the same time each evening.

Taking your tablet(s) at the same time each evening will have the best effect. It will also help you remember when to take the tablets.

How long to take ZIMSTAT

ZIMSTAT helps lower your cholesterol. It does not cure your condition. Therefore, you must continue to take ZIMSTAT 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 ZIMSTAT, your cholesterol levels may rise again.

If you forget to take ZIMSTAT

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 the missed dose as soon as you remember, and then go back to taking your tablet(s) as you would normally.

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

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

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

If you take too much ZIMSTAT

If you think that you have taken too much ZIMSTAT, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, 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 taking ZIMSTAT?

Things you should do

If you become pregnant while you are taking ZIMSTAT, stop taking the medicine and contact your doctor immediately.

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

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

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

If you plan to have elective surgery, including dental surgery, tell your doctor or dentist that you are taking ZIMSTAT.

Your doctor may suggest that you stop taking ZIMSTAT a few days before surgery.

Things you should not do

- **Do not stop taking ZIMSTAT or lower the dose even if you are feeling better, without checking with your doctor.**
- **Do not use ZIMSTAT to treat any other conditions unless your doctor tells you to.**
- **Do not give ZIMSTAT to anyone else, even if they have the same condition as you.**

Things to be careful of

Grapefruit juice should be avoided while taking ZIMSTAT.

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

Changes to lifestyle that may help reduce the chance of coronary heart disease

Lowering high cholesterol can help reduce your chance of having coronary heart disease (CHD). However, your chances of having CHD may be increased by several other factors including high blood pressure, cigarette smoking, diabetes, excess weight, family history of CHD,

being a male and being a woman who has reached menopause.

Some self-help measures suggested below may help your condition and help reduce your chances of having CHD. Talk to your doctor, pharmacist, or dietician about these measures and for more information.

- Diet

continue the low fat diet recommended by your doctor, dietician or pharmacist.

- Weight

your doctor may advise you to lose weight if you are overweight.

- Exercise

make exercise a part of your routine - walking is good. Ask your doctor for advice before starting exercise

- Smoking

your doctor may advise you to stop smoking or at least cut down.

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 ZIMSTAT affects you.

ZIMSTAT may cause dizziness in some people **which may affect your ability to drive or operate heavy machinery.**

Drinking alcohol

Tell your doctor if you drink alcohol.

Avoid drinking large quantities of alcohol.

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

Looking after your medicine

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

Store it in a cool dry place below 25°C 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.

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

If you take the tablets out of the bottle or pack they will not keep well.

Getting rid of any unwanted medicine

If your doctor tells you to stop taking ZIMSTAT 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?

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

Less serious side effects

| Less serious side effects | What to do |
|--|---|
| <ul style="list-style-type: none">• constipation, diarrhoea, wind• stomach upset or pain, feeling sick (nausea) | Speak to your doctor or pharmacist if you have any of these more |

| Less serious side effects | What to do |
|---|---|
| <ul style="list-style-type: none"> ● headache ● dizziness | <p>common side effects and they worry you.</p> <p>For the most part these have been mild and short-lived.</p> |
| <ul style="list-style-type: none"> ● hair loss ● muscle cramps ● trouble sleeping ● poor memory, memory loss, confusion ● depression ● blurred vision and impaired vision ● erectile dysfunction ● breathing problems including persistent cough and/or shortness of breath or fever ● gynaecomastia (breast enlargement in men) ● muscle rupture ● rash that occur on the skin or sores in the mouth (lichenoid drug eruptions) | <p>Speak to your doctor if you notice any of these side effects</p> |

Serious side effects

| Serious side effects | What to do |
|--|---|
| <ul style="list-style-type: none">● tingling in the hands or feet● signs of anaemia, such as tiredness, being short of breath, and looking pale● fever, generally feeling unwell● skin rash, itchiness● pinkish, itchy swellings on the skin, also called hives or nettlerash● painful, swollen joints● bruising more easily than normal● larger breasts than normal in men● weakness in your arms or legs that worsens after periods of activity, double vision or drooping of your eyelids, difficulty swallowing, or shortness of breath (symptoms of myasthenia) | <p>Some of these may be symptoms of an allergic reaction to ZIMSTAT.</p> <p>You may need urgent medical attention or hospitalisation. Serious side effects are rare.</p> <p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> |

| 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 ● shortness of breath | |
| <ul style="list-style-type: none"> ● feel tired or weak ● loss of appetite ● upper belly pain ● dark urine ● yellowing of your skin or the whites of your eyes | <p>Tell your doctor immediately if you have these symptoms of liver problems.</p> <p>Liver problems can occur and may be serious. Your doctor will do a blood test to check your liver.</p> |
| <ul style="list-style-type: none"> ● aching muscles, muscle tenderness or weakness, not caused by exercise ● brown/black coloured urine <p>On rare occasions, muscle problems can be serious, including muscle breakdown resulting in kidney damage that can lead to death.</p> | <p>Tell your doctor immediately if you notice any of the following side effects.</p> <p>These are serious side effects that may require urgent medical attention.</p> |

| Serious side effects | What to do |
|---|-------------------|
| <p>The risk of muscle problems is greater for:</p> <ul style="list-style-type: none"> ● patients taking higher doses of ZIMSTAT, particularly the 80 mg dose ● older patients (65 years of age and older) ● female patients ● patients with abnormal kidney function ● patients with thyroid problems. | |

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

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

Some side effects (for example changes in 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.

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 ZIMSTAT contains

| | |
|---|--|
| Active ingredient (main ingredient) | <ul style="list-style-type: none">● simvastatin 5 mg, 10 mg, 20 mg, 40 mg or 80 mg |
| Other ingredients (inactive ingredients) | <ul style="list-style-type: none">● butylated hydroxyanisole● ascorbic acid● citric acid monohydrate● microcrystalline cellulose● pregelatinised maize starch● magnesium stearate |

| | |
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| | <ul style="list-style-type: none"> ● lactose monohydrate ● purified talc ● ZIMSTAT 5 mg: OPADRY II complete film coating system Y-30-12842-A Yellow (ARTG PI No: 4808) ● ZIMSTAT 10 mg: OPADRY II complete film coating system 32K14826 Pink (ARTG PI No: 4807) ● ZIMSTAT 20 mg: OPADRY II complete film coating system 32K13699 Orange (ARTG PI No: 4806) ● ZIMSTAT 40 mg: OPADRY II complete film coating system 40L14838 Pink (ARTG PI No: 4805) ● ZIMSTAT 80 mg: OPADRY II complete film coating system 32K14826 Pink (ARTG PI No: 4807) |
| Potential allergens | sugars as lactose |

Do not take this medicine if you are allergic to any of these ingredients.

What ZIMSTAT looks like

ZIMSTAT 5 mg - dark, buff coloured, oval-shaped, film-coated tablet with "G" marked on one side and "SM | 5" on the other. (Blister pack - AUST R 95672)

ZIMSTAT 10 mg - dark peach to pink coloured, oval-shaped, film-coated tablet with "G" marked on one side and "SM | 10" on the other. (Blister pack - AUST R 95673)

ZIMSTAT 20 mg - dark tan coloured, oval-shaped, film-coated tablet with "G" marked on one side and "SM | 20" on the other. (Blister pack - AUST R 95674, Bottle - AUST R 95679)

ZIMSTAT 40 mg - pink coloured, oval-shaped, film-coated tablet with "G" marked on one side and "SM40" on the other. (Blister pack - AUST R 95675, Bottle - AUST R 95680)

ZIMSTAT 80 mg - pink to brick-red coloured capsule-shaped, film-coated tablet with "G" marked on one side and "SM80" on the other. (Blister pack - AUST R 95676, Bottle - AUST R 95681)

Each bottle or pack contains 30 tablets.

Who distributes ZIMSTAT

Alphapharm Pty Ltd trading as Viatrix

Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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