

Zimstat

simvastatin

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about Zimstat.

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

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Zimstat against the benefits they expect it will have for you.

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

Keep this leaflet with your medicine.

You may need to read it again.

What Zimstat is used for

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.

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.

Safety and effectiveness have been studied in 10-17 year old boys and in girls, who had started their menstrual period at least one year before (see How to take Zimstat). Zimstat has not been studied in children under the age of 10 years. For more information, talk to your doctor.

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 available only with a doctor's prescription.

Zimstat is not addictive.

Before you take Zimstat

When you must not take it

Do not take Zimstat if:

- **you have an allergy to Zimstat or other brands of simvastatin, or to 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

- **you are pregnant or breastfeeding**

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

- **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**
- **the expiry date on the pack has passed**

If you take this medicine after the expiry date has passed, it may not work.

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 intend to become pregnant or plan to breast feed**

Zimstat should not be used during pregnancy or while breastfeeding.

- **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.**

If you have not told your doctor about any of the above, tell them before you take any Zimstat.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines 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 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, 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.

How to take Zimstat

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

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

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 it

Swallow the tablets with a glass of water.

When to take it

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 it

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 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 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 (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Zimstat. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking Zimstat

Things you must 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 must 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

Avoid drinking large quantities of alcohol.

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

Grapefruit juice should be avoided while taking Zimstat.

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

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

Zimstat generally does not cause any problems with your ability to drive a car or operate machinery.

However, as with many other medicines, Zimstat may cause dizziness in some people. Make sure you know how you react to Zimstat before you drive a car or operate machinery.

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.

Side effects

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

Zimstat 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:

- constipation, diarrhoea, wind
- stomach upset or pain, feeling sick (nausea)
- headache
- dizziness

These are the more common side effects of Zimstat. For the most part these have been mild and short-lived.

Tell your doctor immediately if you notice any of the following:

- aching muscles, muscle tenderness or weakness, not caused by exercise (in very rare cases this may not go away after stopping Zimstat)
- brown/black coloured urine

On rare occasions, muscle problems can be serious, including muscle breakdown resulting in kidney damage that can lead to death.

The risk of muscle problems is greater for:

- 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 immediately if you notice any of the following:

- 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.

These may be serious side effects of Zimstat. Some of these may be symptoms of an allergic reaction to Zimstat. You may need urgent medical attention. Serious side effects are rare.

Tell your doctor immediately or go to accident and emergency at your nearest hospital if you notice any of the following:

- swelling of the face, lips, mouth, throat or tongue which may cause difficulty in swallowing or breathing
- shortness of breath

These are serious side effects. If you have them, you may have had a serious allergic reaction to Zimstat. You may need urgent medical attention or hospitalisation. Serious side effects are rare.

Also, tell your doctor if you notice:

- hair loss
- muscle cramps
- trouble sleeping
- poor memory, memory loss, confusion
- feelings of depression
- erectile dysfunction
- breathing problems including persistent cough and/or shortness of breath or fever

These are other side effects that have been reported with Zimstat.

Liver problems can also occur and may be serious. Your doctor will do a blood test to check your liver.

Tell your doctor immediately 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

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

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

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.

After taking Zimstat

Storage

Keep Zimstat 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.

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.

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

Do not store Zimstat or any other medicine in the bathroom or near a sink.

Do not leave Zimstat in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking Zimstat, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

ZIMSTAT tablets are available in 5 different strengths:

- ZIMSTAT 5 mg - dark, buff coloured, oval-shaped, film-coated tablet with "G" marked on one side and "SM | 5" on the other.
- 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.
- ZIMSTAT 20 mg - dark tan coloured, oval-shaped, film-coated tablet with "G" marked on one side and "SM | 20" on the other.

- ZIMSTAT 40 mg - pink coloured, oval-shaped, film-coated tablet with "G" marked on one side and "SM40" on the other.
- ZIMSTAT 80 mg - pink to brick-red coloured capsule-shaped, film-coated tablet with "G" marked on one side and "SM80" on the other.

Each bottle or pack contains 30 tablets.

Ingredients

Active ingredient:

- ZIMSTAT 5 mg simvastatin per tablet
- ZIMSTAT 10 mg simvastatin per tablet
- ZIMSTAT 20 mg simvastatin per tablet
- ZIMSTAT 40 mg simvastatin per tablet
- ZIMSTAT 80 mg simvastatin per tablet

Inactive ingredients:

- butylated hydroxyanisole
- ascorbic acid
- citric acid monohydrate
- microcrystalline cellulose

- pregelatinised maize starch
- magnesium stearate
- lactose monohydrate
- hypromellose
- titanium dioxide
- purified talc
- triacetin
- iron oxide yellow CI77492, E172 (5 mg, 20 mg and 40 mg tablets)
- iron oxide red CI77491, E172 (10 mg, 20 mg, 40 mg and 80 mg tablets)
- polydextrose FCC (40 mg tablet only)
- macrogol 8000 (40 mg tablet only).

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

Supplier

Zimstat is supplied by:

Alphapharm Pty Limited

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.mylan.com.au

Australian registration numbers:

Zimstat 5:

Blister pack - AUST R 95672

Bottle - AUST R 95677

Zimstat 10:

Blister pack - AUST R 95673

Bottle - AUST R 95678

Zimstat 20:

Blister pack - AUST R 95674

Bottle - AUST R 95679

Zimstat 40:

Blister pack - AUST R 95675

Bottle - AUST R 95680

Zimstat 80:

Blister pack - AUST R 95676

Bottle - AUST R 95681

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