

Zimstat

contains the active ingredient 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 reduce the amount of cholesterol and triglyceride in the blood.

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

Cholesterol is present in many foods and is also made in your body by the liver. If your body does not balance the amount of cholesterol it needs with the amount of cholesterol eaten,

then your cholesterol becomes too high.

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 plaques) on the walls of your blood vessels, making it more difficult for the blood to flow. This blocking of your blood vessels can lead to heart disease (such as heart attack and angina) and stroke.

In patients with coronary heart disease (CHD) accompanied by high cholesterol levels, Zimstat may slow down the hardening of blood vessels and reduce the risk of new plaque formation.

If you have CHD, your doctor has prescribed Zimstat to help prolong your life and lessen the risk of heart attack or prevent further attacks or stroke. Zimstat may also decrease the risk of needing an operation to increase the blood flow to your heart.

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

Triglycerides are an energy source for the body. However, as with cholesterol, high levels of triglycerides in your blood can be a problem.

How Zimstat works.

Zimstat belongs to a group of medicines known as HMG-CoA reductase inhibitors (also known as "statins"). The medicine works by reducing the amount of cholesterol made by the liver. More specifically, Zimstat reduces the amount of LDL (bad cholesterol) and raises the amount of HDL (good cholesterol).

As Zimstat does not reduce the cholesterol and triglycerides that come from the fat in the food, you need to combine Zimstat with a low fat diet. You should also undertake an exercise and weight control program.

In most people there are no symptoms of high cholesterol or triglycerides. However, they can be measured by a simple blood test, which your doctor can do.

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

Your doctor may have prescribed Zimstat for another reason.

Zimstat has not been studied in children under the age of 10 years. For more information, talk to your doctor.

Zimstat is available only with a doctor's prescription.

There is no evidence that Zimstat is addictive.

Before you take Zimstat

When you must not take it

Do not take Zimstat if you are allergic to medicines containing simvastatin or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching or hives; swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, wheezing or shortness of breath.

Do not take Zimstat if you have:

- * liver disease
- * had muscle pain, tenderness or weakness caused by other medicines used to treat high cholesterol or triglycerides e.g., atorvastatin (Lipitor) and pravastatin (Pravachol).

Do not take Zimstat if you are pregnant.

Zimstat may harm your developing baby if you take it during pregnancy.

If you are a woman able to have children and are not using an effective contraceptive (e.g., birth control pill), do not take Zimstat.

Do not take Zimstat if you are breastfeeding.

Zimstat passes into breast milk and may harm your baby.

Do not take Zimstat if the expiry date (EXP.) printed on the bottle or pack has passed.

Do not take Zimstat if the packaging shows signs of tampering or the tablets do not look quite right.

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 including Lipex (which is another brand of simvastatin)
- * any other substances, such as foods, preservatives or dyes

Tell your doctor if you plan to become pregnant or breastfeed.

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

- * liver disease
- * kidney problems

Your doctor may want to take special care if you have any of these conditions.

Tell your doctor if you drink alcohol regularly.

Tell your doctor if you plan to have surgery.

Your doctor may suggest stopping the tablets a few days before surgery.

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

Taking other medicines

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

Some medicines may be affected by Zimstat, or may affect how well it works. These include:

- * other medicines used to lower cholesterol levels, for example, gemfibrozil (Jezil, Lopid) or large doses (= 1 g/day) of nicotinic acid (also known as niacin)
- * warfarin, used to prevent clots
- * erythromycin, clarithromycin and fusidic acid antibiotics used to treat infections
- * ketoconazole (Nizoral) and itraconazole (Sporanox), used to treat certain fungal infections

- * cyclosporin, used to suppress the immune system
- * nefazodone (Serzone), used for treatment of depression
- * protease inhibitors which are used to treat HIV infections including indinavir, nelfinavir, ritonavir and saquinavir
- * verapamil, used to treat high blood pressure and angina
- * amiodarone, used to treat severe tachyarrhythmias
- * diltiazem, used for hypertension and angina
- * digoxin, used for congestive heart failure and atrial fibrillation
- * danazol, used for endometriosis, menorrhagia and angioedema.

Your doctor can tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while 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 on the bottle or pack, ask your doctor or pharmacist.

How much to take

The dose varies from patient to patient and depends on your level of cholesterol and triglyceride as well as other factors such as liver disease.

The usual 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 treat the disease most effectively.

People with other risk factors for heart disease may be started on 40 mg per day (taken in the evening).

How to take it

Swallow the tablets with a glass of water.

When to take it

Zimstat is normally taken once daily, in the evening.

The best time to take Zimstat is in the evening, when the body is at rest and there is no food intake as this is the time that the liver produces the most amount of cholesterol.

Take Zimstat at about the same time each night.

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

How long to take it for

Keep taking Zimstat for as long as your doctor recommends.

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 tablets 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 any questions about this, check with your doctor or pharmacist.

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think 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 taking Zimstat, stop taking the medicine and contact your doctor immediately.

Before starting any other new medicine, tell your doctor or pharmacist that you are taking Zimstat.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Zimstat.

If you plan to have 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.

Visit your doctor regularly so they can check on your progress.

To make sure that Zimstat is working, have your blood fats checked when your doctors asks you to.

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.

Avoid drinking large quantities of grapefruit juice.

Grapefruit juice contains one or more constituents that can alter how well a drug, like Zimstat, works. Therefore, drinking very large quantities of grapefruit juice (over 1 litre) increases the chance of Zimstat causing side effects (including aching muscles, muscle tenderness or weakness not caused by exercise). However, one glass of grapefruit juice (250 mL) each day has not been shown to have any significant effect.

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.

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

Lowering high cholesterol can help reduce your chances of having Coronary Heart Disease (CHD). However, your chances of having CHD may be increased by several other factors including high blood pressure, being a male, cigarette

smoking, diabetes, excess weight, family history of CHD 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 will advise you to stop smoking.

Side effects

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

Like all other medicines, Zimstat may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

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

Tell your doctor immediately or go to Accident and Emergency at the 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.

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

- * aching muscles, muscle tenderness or weakness, not caused by exercise
- * tingling in the hands or feet
- * yellowing of the skin and/or eyes, also called jaundice
- * 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
- * increased breast size in men.

The above list includes serious side effects. Some of these may be symptoms of an allergic reaction to Zimstat. You may require urgent medical attention. Serious side effects are rare.

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

- * constipation, diarrhoea, wind
- * stomach upset or pain, feeling sick (nausea)
- * headache
- * dizziness
- * difficulty sleeping
- * memory loss.

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

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

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. 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.

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 degrees 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 oval-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
- * cellulose - microcrystalline
- * starch - pregelatinised maize

- * magnesium stearate
- * lactose
- * hypromellose
- * titanium dioxide
- * talc purified
- * glycerol triacetate
- * 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
(ABN 93 002 359 739)
Chase Building 2
Wentworth Park Road
Glebe NSW 2037

Phone: (02) 9298 3999

www.alphapharm.com.au

Medical Information

Phone: 1800 028 365

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

This leaflet was prepared on
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