

NEW ZEALAND CONSUMER MEDICINE INFORMATION

LORSTAT

Atorvastatin tablets 10 mg, 20 mg, 40 mg & 80 mg



What is in this leaflet

Please read this leaflet carefully before you start taking Lorstat.

This leaflet answers some common questions about Lorstat.

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 Lorstat 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 Lorstat is used for

Lorstat is used to treat lower high cholesterol levels.

Lorstat is also used in people who have high blood pressure and coronary heart disease (CHD) or who are at risk of CHD (for example, if they have diabetes, a history of stroke, or small blood vessel disease). In these people, Lorstat is used to reduce the risk of having a heart attack or stroke.

How Lorstat works

Lorstat contains the active ingredient *atorvastatin calcium*. It belongs to a group of medicines called HMG-CoA reductase inhibitors (also known as "statins")

It works by reducing the amount of cholesterol made by the liver. More

specifically, Lorstat reduces the amount of LDL (bad cholesterol) and raises the amount of HDL (good cholesterol). Lorstat also helps to protect you from a heart attack or stroke.

What is cholesterol

Everyone has cholesterol and triglycerides 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 triglycerides 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.

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.

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 blood vessel disease, heart disease (such as heart attack and angina) and stroke.

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

In some patients, Lorstat is used to treat high cholesterol and high triglycerides together.

When you are taking Lorstat, 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. However, they can be measured by a simple blood test, which your doctor can do.

Your doctor may have prescribed this medicine for another reason.

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

Lorstat has been studied to a very limited extent in children. For more information talk to your doctor.

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

There is no evidence that Lorstat is addictive.

Before you take Lorstat

When you must not take it

Do not take Lorstat if you have an allergy to:

- any medicine containing atorvastatin.
- 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 Lorstat if you have active liver disease.

Do not take this medicine if you are pregnant or intend to become pregnant.

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

Women of child-bearing age who are taking the medicine should use a proven method of birth control to avoid pregnancy.

Do not take the medicine if you are breastfeeding or intend to breastfeed.

The medicine may pass into breast milk and affect your baby.

Do not take Lorstat if you are taking the antibiotic fusidic acid, which is used to treat infections.

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:

- any medical conditions including:
 - liver problems
 - kidney problems
 - lung problems
 - hormonal problem
 - muscle pain, tenderness or weakness from other medicines used to treat

cholesterol or triglycerides.

- a history of haemorrhagic stroke, or lacunar stroke.
- drink alcohol regularly.
- any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.

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

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 Lorstat.

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 Lorstat.

Some medicines may interfere with Lorstat. These include:

- digoxin, a medicine used to treat some heart problems.
- antibiotics, such as erythromycin, clarithromycin, rifampicin and fusidic acid.
- phenytoin, a medicine used to treat epilepsy.
- oral contraceptives for birth control.
- other medicines used to treat high cholesterol or triglycerides.
- antacids, medicines used to treat reflux or ulcers.
- ciclosporin, a medicine used to suppress the immune system.
- protease inhibitors which are used to treat HIV infections, such as efavirenz, ritonavir and boceprevir, simeprevir, and elbasvir/grazoprevir.
- ketoconazole and itraconazole, used to treat certain fungal infections.

- diltiazem, a medicine used to treat angina.
- spironolactone a medicine used to treat high blood pressure and certain types of swelling.
- vitamin B3.
- colchicine, a medicine used to treat gout, a disease with painful, swollen joints caused by uric acid crystals.
- ticagrelor, a medicine used to reduce the risk of stroke or heart attack.
- letermovir, an antiviral medicine used to treat CMV infections.

These medicines may be affected by Lorstat 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 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 this medicine.

How to take Lorstat

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

Take Lorstat only when prescribed by your doctor.

The usual dose of Lorstat is between 10-80 mg taken once a day.

How to take it

Swallow the tablets whole with a full glass of water, with or without food.

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.

How long to take it

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

Lorstat helps lower your cholesterol. It does not cure your condition. Therefore, you must continue to take Lorstat as directed by your doctor if you expect to lower your cholesterol and keep it down.

Continue taking your medicine until you finish the pack.

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 Lorstat

Things you must do

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

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 Lorstat, stop taking the medicine and contact 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 liver function tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Your cholesterol and triglycerides levels also need to be checked regularly while you are taking Lorstat.

Things you must not do

Do not take Lorstat 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.

If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects such as

If possible, your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

Things to be careful of

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

Lorstat generally does not cause any problems with your ability to drive a car or operate machinery. However, as with many other

medicines, Lorstat may cause dizziness in some people.

Avoid drinking large quantities of alcohol.

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

Avoid drinking large quantities of grapefruit juice. Grapefruit juice contains one or more components that alter the metabolism of some medicines, including Lorstat.

Therefore, drinking very large quantities of grapefruit juice (over 1 litre) each day increases the chance of Lorstat causing side effects.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons 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 Lorstat. 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 Lorstat.

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:

- muscle and muscle weakness
- joint pain and swollen joints
- constipation, diarrhoea
- unusual tiredness or weakness
- stomach or belly pain, nausea
- heartburn, indigestion or wind
- headache
- urine infection
- nose bleeds, stuffy or runny nose
- rash
- blurred vision
- problems with breathing such as breathlessness, wheezing, chest tightness and cough
- erectile dysfunction
- male breast enlargement
- loss of appetite
- nightmare
- belching
- symptoms of hyperglycaemia, such as increase urine, thirst, dry mouth or skin
- trouble sleeping
- unusual hair loss
- loss of memory
- dizziness.

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

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

- symptoms of an allergy such as skin rash, itching, swelling of the face, lips, mouth, tongue, throat or neck which may cause difficulty in swallowing and breathing
- chest pain
- fever

- yellowing of the skin and eyes and dark colored urine
- unexpected muscle pain, tenderness or weakness not caused by exercise
- sudden severe headache
- nausea
- vomiting
- loss of sensation
- tingling in any parts of your body
- ringing in the ears
- severe blisters and bleeding of the lips, eyes, mouth, nose or genitals.

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

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 of these side effects (for example, cholesterol level) 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 Lorstat

Storage

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

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

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

Do not store Lorstat 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

Lorstat tablets are available in 4 different strengths:

Lorstat 10 mg – White, oval, biconvex, film coated tablet, plain on one side and debossed “10” on the other side.

Lorstat 20 mg - White, oval, biconvex, film coated tablet, with breakline on one side and debossed “20” on the other side.

Lorstat 40 mg - White, oval, biconvex, film coated tablet, with breakline on one side and debossed “40” on the other side.

Lorstat 80 mg – White, oval, biconvex, film coated tablet, with breakline on one side and debossed “80” on the other side.

Ingredients

Active ingredient(s):

Lorstat contains 10, 20, 40, or 80 mg of *atorvastatin calcium* as the active ingredient.

Inactive ingredient(s):

Lorstat also contains:

- colloidal anhydrous silica
- sodium carbonate
- microcrystalline cellulose
- L-arginine
- lactose
- croscarmellose sodium
- hydroxypropyl cellulose
- magnesium stearate
- Opadry AMB White OY-B-28920 (containing titanium dioxide, talc, xanthan, gum, polyvinyl alcohol and soya lecithin).
- Opadry II white 85F18378 (containing polyvinyl alcohol – part hydrolysed, titanium dioxide, macrogol and talc)

Lorstat tablets may be coated with either Opadry AMB White OY-B-28920 or Opadry II white 85F18378.

If you want to know more

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

Who supplies this medicine

Lorstat is supplied in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland
NEW ZEALAND

Telephone: 0800 579 811

Date of Preparation

4 May 2021
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