LORSTAT®

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 LORSTAT?

LORSTAT contains the active ingredient atorvastatin (as calcium trihydrate). LORSTAT is used to lower high cholesterol levels. It is also used to help reduce the risk of having a heart attack or stroke in people who have high blood pressure and coronary heart disease (CHD) or who are at risk of CHD. For more information, see Section 1. Why am I taking LORSTAT? in the full CMI.

2. What should I know before I take LORSTAT?

Do not use if you have ever had an allergic reaction to atorvastatin 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 LORSTAT? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with LORSTAT 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 LORSTAT?

- The usual dose of LORSTAT is between 10-80 mg taken once a day.
- Swallow the tablets whole with a full glass of water. Do not chew or crush the tablets.

More instructions can be found in Section 4. How do I take LORSTAT? in the full CMI.

5. What should I know while taking LORSTAT?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using LORSTAT. • Keep all of your doctor's appointments so that your progress can be checked.
Things you should not do	• Do not stop taking your medicine or change the dosage without checking with your doctor. • Do not give LORSTAT to anyone else, even if they have the same condition as you.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how LORSTAT affects you. • LORSTAT may cause dizziness in some people.
Drinking alcohol	• Avoid drinking large quantities of alcohol as this may increase your chance of liver problems.
Looking after your medicine	• Keep your tablets in a cool dry place where the temperature stays below 25°C. • Keep LORSTAT where children cannot reach it.

For more information, see Section 5. What should I know while taking LORSTAT? in the full CMI.

6. Are there any side effects?

Less serious side effects: muscle and joint pain, muscle weakness, especially in the forearms, thighs, hips, shoulders, neck, and back; difficulty climbing stairs or standing up from a chair; difficulty lifting arms over the head; difficulty getting up from a fall; constipation, diarrhoea; stomach pain, nausea (feeling sick); heartburn, indigestion; urine infection; headache; stuffy or runny nose; nose bleeds, foul, salty or metallic taste. **Serious side effects:** yellowing of the skin and eyes and dark coloured urine; feeling weak, excessively thirsty and passing more urine; problems with breathing, including shortness of breath, persistent cough and fever; vision problems, eye muscle weakness and drooping eyelid; depression, red spots or lumps on the skin, which could be signs of vasculitis (narrowing or blockage of blood vessels). **Very serious side effects:** symptoms of allergy such as skin rash, itching, swelling of the face, lips, mouth, throat or neck which may cause difficulty in swallowing or breathing; chest pain; unexpected muscle pain, tenderness or weakness not caused by exercise; sudden severe headache, which may be accompanied by nausea, vomiting, loss of sensation, tingling in any part of the body or ringing in the ears; severe blisters and bleeding of the lips, eyes, mouth, nose or genitals.

This is not a complete list of all possible side effects. 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.

LORSTAT®

Active ingredient: *atorvastatin (as calcium trihydrate)*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

1. Why am I taking LORSTAT?
2. What should I know before I take LORSTAT?
3. What if I am taking other medicines?
4. How do I take LORSTAT?
5. What should I know while taking LORSTAT?
6. Are there any side effects?
7. Product details

1. Why am I taking LORSTAT?

LORSTAT contains the active ingredient atorvastatin (as calcium trihydrate).

LORSTAT belongs to a group of medicines known as HMG-CoA reductase inhibitors. It works by reducing the amount of cholesterol made by the liver.

LORSTAT reduces the 'bad' cholesterol and can raise the 'good' cholesterol. LORSTAT also helps to reduce the risk of having a heart attack or stroke in people who have high blood pressure and coronary heart disease (CHD) or who are at risk of CHD.

Examples of risk factors for CHD include diabetes, a history of stroke, or small blood vessel disease.

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

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

What is cholesterol?

Everyone has cholesterol in their blood. It is a type 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 can be a problem.

Cholesterol is present in many foods and is also made in your body by the liver. If your body makes too much cholesterol or you have too much cholesterol in your diet, then your level 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. LDL, or low-density lipoprotein, is the 'bad' cholesterol that can block your blood vessels. HDL, or high-density lipoprotein, cholesterol is the 'good' cholesterol that is thought to remove the 'bad' cholesterol from the blood vessels.

When you have high levels of 'bad' cholesterol in your blood, 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. Sometimes, the plaque can detach from the vessel wall and float in the bloodstream; it can then reach a smaller vessel and completely block it. This blocking of your blood vessels can lead to several types of blood vessel disease, heart attack, angina and stroke.

There is another type of blood fat called triglyceride, which is a source of energy. However, high levels of triglyceride can be associated with a low level of 'good' cholesterol and may increase your risk of heart disease.

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

In most people, there are no symptoms of abnormal cholesterol or triglyceride levels. Your doctor can measure your levels with a simple blood test.

When you are taking LORSTAT, you also need to follow a low-fat diet and other measures, such as exercise and weight control.

LORSTAT may be used alone, or in combination with other medicines, to treat your condition.

2. What should I know before I take LORSTAT?

Warnings

Do not take LORSTAT if you:

- are allergic to atorvastatin, 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.
- have active liver disease
- are pregnant or intend to become pregnant
- are breastfeeding
- are taking the antibiotic fusidic acid hemihydrate which is used to treat infections
- are taking the antivirals glecaprevir/pibrentasvir for the treatment of Hepatitis C.

Do not give this medicine to a child.

Information of safety and effectiveness in children is limited.

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.

Check with your doctor if you:

- have allergies to any other medicines, foods, preservatives or dyes
- take any medicines for any other condition
- have or have had any of the following medical conditions:
    - liver problems
    - kidney problems
    - muscle pain, tenderness or weakness from other medicines used to treat high cholesterol or triglycerides
    - vision problems, eye muscle weakness and drooping eyelid
    - a type of stroke called a haemorrhagic stroke, or a type of stroke called a lacunar stroke
      If you have had one of these strokes before, this medicine may increase the risk of you having a haemorrhagic stroke
    - breathing problems
- drink alcohol regularly
- you are pregnant or plan to become pregnant or are breastfeeding

Your doctor will ask you to have your liver function tested before you start to take LORSTAT.

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

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

If you are a woman of child-bearing age and are taking this medicine, use a proven method of birth control to avoid pregnancy.

This medicine may affect your developing baby if you take it during pregnancy.

Do not breastfeed if you are taking this medicine.

The active ingredient in LORSTAT may pass into breast milk and affect your baby.

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.

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 may interfere with LORSTAT and affect how it works. You may need different amounts of your medicines, or you may need to take different medicines. These include:

- digoxin, a medicine used to treat some heart problems
- diltiazem, a medicine used to treat angina
- other medicines to treat high cholesterol or triglycerides (fats)
- antacids, medicines used to treat reflux or ulcers
- the antibiotics erythromycin, clarithromycin, rifampicin, daptomycin or fusidic acid hemihydrate
- phenytoin, a medicine used to treat epilepsy (seizures)
- oral contraceptives for birth control
- ciclosporin, a medicine used to suppress the immune system
- some medicines used to treat some fungal infections such as itraconazole and ketoconazole
- protease inhibitors for the treatment of HIV infection and/or Hepatitis C such as efavirenz, fosamprenavir, ritonavir, boceprevir, telaprevir, tipranavir/ritonavir, elbasvir/grazoprevir and simeprevir
- HCV non structural protein 5A (NS5A)/5B (NS5B) inhibitors such as daclatasvir and ledipasvir
- letermovir
- spironolactone, a medicine used to treat high blood pressure and certain types of swelling
- vitamin B3
- colchicine, a medicine used to treat a disease with painful, swollen joints caused by uric acid crystals
- ticagrelor, a medicine used to prevent blood clots.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

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

4. How do I take LORSTAT?

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 these instructions, ask your doctor or pharmacist for help.

How much to take

- Take LORSTAT only when prescribed by your doctor.
- Your doctor will tell you how many tablets you need to take each day. This may depend on your condition and whether or not you are taking any other medicines.
- The usual dose of LORSTAT is between 10-80 mg taken once a day.
- Follow the instructions provided and use LORSTAT until your doctor tells you to stop.

When to take LORSTAT

- LORSTAT should be taken 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.
- LORSTAT can be taken with or without food.

How to take LORSTAT

- Swallow the tablets whole with a full glass of water.
- **Do not crush or chew the tablets.**
- Your doctor will discuss with you the need to be on a diet while you are taking LORSTAT.
  Follow your agreed diet plan carefully.

How long to take LORSTAT

- Continue taking your medicine for as long as your doctor tells you to.
- This medicine helps to lower your levels of cholesterol, but does not cure your condition. It is important to keep taking your medicine even if you feel well.
- If you stop taking LORSTAT, your cholesterol levels may rise again.

If you forget to take LORSTAT

LORSTAT should be used regularly at the same time each day.

If you miss your dose at the usual time and it is less than 12 hours before 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 you missed.

This may increase the chance of you getting unwanted side effects.

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.

If you take too much LORSTAT

If you think that you or anyone else have used too much LORSTAT, urgent medical attention may be needed.

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 LORSTAT?

Things you should do

- Keep all of your doctor's appointments so that your progress can be checked.
- Your doctor will ask you to have your liver function tested from time to time while you are taking LORSTAT to make sure the medicine is working and to prevent unwanted side effects.
- Your cholesterol and triglyceride levels also need to be checked regularly while you are taking this medicine.
- A regular blood test to check an enzyme called creatine kinase (CK) may be needed. CK in your blood can rise after muscle injury which can be caused by medicines used to treat cholesterol or triglycerides, such as LORSTAT.
- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking LORSTAT.
- 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 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.

Call your doctor straight away if you:

- become pregnant while taking LORSTAT. Stop taking it and contact your doctor immediately.

Things you should not do

- Do not stop taking your medicine or change the dosage without checking with your doctor.
- 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.

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

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

Drinking grapefruit juice

Avoid drinking large quantities of grapefruit juice.

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

Drinking very large quantities of grapefruit juice (over 1.2 liters) each day while taking LORSTAT increases your chance of getting side effects.

Driving or using machines

Be careful before you drive or use any machines or tools 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.

If you feel dizzy, do not drive, operate machinery or do anything else that could be dangerous.

Drinking alcohol

Avoid drinking large quantities of alcohol.

Drinking large quantities of alcohol while taking LORSTAT may increase your chance of getting liver problems.

Tell your doctor if you drink alcohol regularly.

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.

Things that would be helpful for your condition

Some self-help measures suggested below may help your condition. Your doctor or pharmacist can give you more information about these measures.

- **Weight:** While you are taking LORSTAT, you need to follow a diet plan agreed to with your doctor. This may include measures to lose some weight.
- **Exercise:** Regular exercise can help lower your cholesterol levels. It is important not to overdo it. Before commencing regular exercise, you should consult your doctor who will suggest the most suitable exercise for you. If you experience any discomfort when exercising, see your doctor.
- **Reduce Alcohol:** Excessive alcohol intake can raise your cholesterol levels or affect your liver function, which could increase the chance of you getting unwanted side effects. Your doctor may discuss with you whether you should reduce the amount of alcohol you drink.
- **Avoid Smoking:** Smoking increases the risk of you suffering from heart problems. Your doctor may advise you to stop smoking.

Looking after your medicine

- **Keep your tablets in the blister/bottle until it is time to take them.**
  If you take the tablets out of the pack/bottle they may not keep well.
- Keep your tablets in a cool dry place where the temperature stays below 25°C.

Follow the instructions on the container 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 meters 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?

This medicine helps most people with lowering high cholesterol levels and reducing the risk of having a heart attack or stroke in people who have high blood pressure and coronary heart disease (CHD) or who are at risk of CHD, but it may have unwanted side effects in some 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.

Do not be alarmed by the following list of side effects. You may not experience any of them.

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
• muscle and joint pain, muscle weakness, especially in the forearms, thighs, hips, shoulders, neck, and back • difficulty climbing stairs or standing up from a chair • difficulty lifting arms over the head • falling and difficulty getting up from a fall • constipation, diarrhoea • stomach or belly pain, nausea (feeling sick) • heartburn, indigestion or wind • urine infection • headache • stuffy or runny nose • nose bleeds • foul, salty or metallic taste	**Speak to your doctor if you have any of these less serious side effects and they worry you.** This list includes the more common side effects of your medicine. They are usually mild and short-lived.

Serious side effects

Serious side effects	What to do
• yellowing of the skin and eyes and dark coloured urine • feeling weak and tired, excessively thirsty and passing more urine • problems with breathing, including shortness of breath, persistent cough and fever	**Call your doctor straight away if you notice any of these serious side effects.**

Serious side effects	What to do
• vision problems, eye muscle weakness and drooping eyelid • depression • red spots or lumps on the skin, which could be signs of vasculitis (narrowing or blockage of blood vessels). • skin rashes	This list includes serious side effects that may require medical attention. Serious side effects are rare.

Very Serious side effects

Serious side effects	What to do
• symptoms of allergy such as skin rash, itching, swelling of the face, lips, mouth, throat or neck which may cause difficulty in swallowing or breathing • chest pain • unexpected muscle pain, tenderness or weakness not caused by exercise, particularly if you also feel unwell or have a fever • sudden severe headache, which may be accompanied by nausea, vomiting, loss of sensation, tingling in any part of the body or ringing in the ears • severe blisters and bleeding of the lips, eyes, mouth, nose or genitals	**Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.** This list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

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 of these side effects (for example, changes in thyroid function, cholesterol level or blood pressure) can only be found when your doctor does tests from time to time to check your progress.

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 LORSTAT contains

Active ingredient (main ingredient)	atorvastatin (as calcium trihydrate)
Other ingredients (inactive ingredients)	• colloidal anhydrous silica • sodium carbonate • microcrystalline cellulose • arginine • lactose • croscarmellose sodium • hyprolose • magnesium stearate • Opadry II complete film coating system 85F18378 WHITE (ID 12315)
Potential allergens	sugars as lactose

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

What LORSTAT looks like

LORSTAT 10 mg: white, oval, biconvex, film coated tablet plain on one side and debossed '10' on the other side (Blister - AUST R 334865; Bottle - AUST R 334861).

LORSTAT 20 mg: white, oval, biconvex, film coated tablet with break line on one side and debossed '20' on the other side (Blister - AUST R 334862; Bottle - AUST R 334868).

LORSTAT 40 mg: white, oval, biconvex, film coated tablet with break line on one side and debossed '40' on the other side (Blister - AUST R 334863; Bottle - AUST R 334867).

LORSTAT 80 mg: white, oval, biconvex, film coated tablet with break line on one side and debossed '80' on the other side (Blister - AUST R 334864; Bottle - AUST R 334866).

Who distributes LORSTAT

Alphapharm Pty Ltd trading as Viatris

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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