CAVSTAT

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 CAVSTAT?

CAVSTAT contains the active ingredient rosuvastatin calcium. CAVSTAT is used to lower high cholesterol levels. Even though you may have normal cholesterol, CAVSTAT can also be used to reduce the risk of you having a stroke or heart attack. For more information, see Section 1. Why am I taking CAVSTAT? in the full CMI.

2. What should I know before I take CAVSTAT?

Do not take if you have ever had an allergic reaction to CAVSTAT or any of the ingredients listed at the end of the CMI, or if you become pregnant while you are taking CAVSTAT. **Talk to your doctor if you have any other medical conditions, take any other medicines, are pregnant, plan to become pregnant or are breastfeeding.** For more information, see Section 2. What should I know before I take CAVSTAT? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with CAVSTAT 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 CAVSTAT?

- The usual dose is 5 mg to 20 mg taken once daily, but some patients may need to increase this to 40 mg once daily. Your doctor will monitor your cholesterol and triglyceride levels during your treatment and, if needed, may increase your dose.
- Swallow each tablet whole with a drink of water. You can take your tablet at any time of the day, with or without food. More instructions can be found in Section 4. How do I take CAVSTAT? in the full CMI.

5. What should I know while taking CAVSTAT?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are taking CAVSTAT. • Have your blood cholesterol and triglycerides checked when your doctor says so • Stop taking CAVSTAT and seek medical attention immediately if you experience any of the serious side effects listed in Section 6 in the full CMI.
Things you should not do	• Do not stop taking CAVSTAT unless you have discussed it with your doctor.
Driving or using machines	• Be careful driving a car or operating machinery as CAVSTAT may cause dizziness in some people.
Drinking alcohol	• Excessive alcohol consumption may not be safe in patients taking CAVSTAT.
Looking after your medicine	• Keep your tablets in the blister pack until it is time to take them. Store your medicine in a cool dry place below 25°C. Keep your medicine where children cannot reach it.

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

6. Are there any side effects?

The most common side effects of CAVSTAT are headache, constipation, dizziness, nausea, stomach pain, unusual tiredness or a general feeling of weakness, muscle pain, and stiff or painful joints. Tell your doctor if you notice a significant increase in your need to urinate or if you are significantly more hungry or thirsty than usual. Seek medical attention immediately if you experience any of the following, particularly if you also generally feel unwell: muscle aches, tenderness or weakness not caused by exercise particularly if you also have fever; difficulty breathing, coughing, swelling of the face, eyelids or lips; widespread rash, high body temperature, enlarged lymph nodes; or skin rash or sores in the mouth. 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.

CAVSTAT

Active ingredient(s): rosuvastatin calcium

Consumer Medicine Information (CMI)

This leaflet provides important information about taking CAVSTAT. **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 CAVSTAT.**

Where to find information in this leaflet:

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

1. Why am I taking CAVSTAT?

CAVSTAT contains the active ingredient rosuvastatin calcium. CAVSTAT belongs to a group of medicines known as HMG-CoA reductase inhibitors (also known as 'statins'). It lowers the "bad" cholesterol (LDL), and raises the "good" cholesterol (HDL) when exercise and changes to diet are not enough on their own.

CAVSTAT is used to lower high cholesterol levels.

Even though you may have normal cholesterol, CAVSTAT can also be used to reduce the risk of you having a stroke or heart attack if you are a man 50 or more years old or a woman 60 or more years old and have at least 2 risk factors for having a heart attack or stroke, such as high blood pressure, low levels of good cholesterol, smoking or a family history of premature coronary heart disease. Your doctor may also do a blood test to measure a substance called C Reactive Protein to help decide if you should be given CAVSTAT for this use.

Cholesterol and triglycerides

Everyone has cholesterol and triglycerides in their blood. They are fatty substances needed by the body for many things.

Triglycerides are an energy source for the body. Cholesterol is essential for building cells, making bile acids (which help to digest foods) and making some hormones.

There are different types of cholesterol. Too much of the "bad" cholesterol can block the blood vessels that supply your heart and brain with blood, and can cause heart attack, angina and stroke. The "good" cholesterol helps to remove the bad cholesterol from the blood vessels. High levels of triglycerides can be associated with a low level of "good" cholesterol and may increase the risk of heart disease.

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

Cholesterol is present in many foods and is also made by your body. CAVSTAT does not reduce the cholesterol that comes from fat in food. Because of this, when you are taking CAVSTAT, you need to follow a low-fat diet, control your weight and exercise regularly.

2. What should I know before I take CAVSTAT?

Warnings

Do not take CAVSTAT if:

- you are allergic to rosuvastatin calcium, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can take this medicine.
- you are pregnant, become pregnant while taking CAVSTAT, are breastfeeding, or trying to become pregnant unless you are taking adequate contraceptive precautions
- you have active liver disease or if tests show you have elevated levels of liver enzymes which may show that you have a problem with your liver.

Do not take CAVSTAT 40 mg if you have:

- low thyroid hormone levels (hypothyroidism)
- a personal or family history of hereditary muscular disorders
- a previous history of muscular problems from using other lipid-lowering agents
- a history of very heavy alcohol use
- Asian heritage
- been prescribed another class of lipid lowering agent called a fibrate
- been prescribed any medicine containing fusidic acid
- severe kidney impairment
- situations that may increase CAVSTAT blood levels

Pregnancy and breastfeeding

Do not take CAVSTAT if you are pregnant or intend to become pregnant. Ask your doctor about effective methods of contraception.

If you become pregnant, stop taking CAVSTAT as soon as you find out and see your doctor immediately.

Do not take CAVSTAT if you are breastfeeding. Your baby may absorb this medicine from breast milk and there is a possibility of harm to the baby.

Check with your doctor if you:

- have allergies to any other statins such as simvastatin, pravastatin, atorvastatin, or fluvastatin. If you have an allergic reaction, you may get a skin rash, hay fever, difficulty in breathing or feel faint.
- have any of these medical conditions:
    - liver problems
    - kidney problems

- low thyroid hormone levels (hypothyroidism)
- a personal or family history of muscle disorders
- a history of muscle problems from using other lipid-lowering agents.

It may not be safe for you to take CAVSTAT if you have any of these conditions. Your doctor may do a blood test to check if you have any problems, and may adjust the dose of CAVSTAT.

- have any unexplained aches or pains in your muscles.
- regularly drink large amounts of alcohol. Excessive alcohol consumption may not be safe in patients taking CAVSTAT.

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?

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 CAVSTAT and affect how it works. These include:

- ciclosporin, used for example, after organ transplant
- belumosudil, used to treat chronic graft-versus-host disease
- antacids, used to treat heartburn and indigestion; CAVSTAT can be taken 2 hours before or 2 hours after taking an antacid
- warfarin, used to stop blood clots
- clopidogrel or ticagrelor, used to prevent blood clots
- gemfibrozil, fenofibrate or ezetimibe, used to lower blood lipids
- fusidic acid, used to treat some infections
- febuxostat, used to treat and prevent high blood levels of uric acid
- teriflunomide, used to treat relapsing remitting multiple sclerosis
- antiviral medications (alone or in combination), such as atazanavir, darunavir, glecaprevir, lopinavir, pibrentasvir, ritonavir, sofosbuvir, velpatasvir, and voxilaprevir, grazoprevir, elbasvir, ombitasvir, paritaprevir, dasabuvir used to fight infections, including the HIV infection
- momelotinib, used to treat myelofibrosis, a rare form of blood cancer
- roxadustat or vadadustat (medicines that increase the number of red blood cells and haemoglobin level in chronic kidney disease patients)
- enasidenib (used to acute myeloid leukemia)
- anti-cancer medications, such as capmatinib, regorafenib and darolutamide, used to treat cancer
- eltrombopag, used to increase your platelet count in your blood
- tafamidis, used to treat a protein disorder.

Your doctor will consider if CAVSTAT should be taken together with any of these medicines, or may wish to adjust the dose of CAVSTAT or the other medicines. These medicines may affect the way CAVSTAT works.

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

4. How do I take CAVSTAT?

How much to take

- Depending on your condition and ethnic background, your doctor will decide the most appropriate starting dose for you.
- If you have high cholesterol, your doctor will probably start you on a 5 mg or 10 mg tablet taken once daily. Your doctor will then monitor your cholesterol and triglyceride levels during your treatment and, if needed, may increase your CAVSTAT dose to 20 mg once daily. For most patients a maximum 20 mg CAVSTAT daily dose is sufficient to treat high cholesterol.
- A small number of patients may need to further increase their CAVSTAT dose to 40 mg once daily, for example patients whose high cholesterol is hereditary.
- If your cholesterol is not high but you have risks for having a heart attack or stroke, your doctor may start you on 20 mg.
- Your doctor will advise you on the dose that's right for your condition. The daily dose of CAVSTAT must not exceed 40 mg daily.

  DO NOT INCREASE OR ADJUST YOUR CAVSTAT DOSE YOURSELF.

- Swallow each tablet whole with a drink of water.
- You must continue to take it as directed.
- CAVSTAT helps lower your blood cholesterol and triglycerides. It does not cure your condition. If you stop taking CAVSTAT, your cholesterol and triglycerides levels may rise again.
- You may have to take cholesterol-lowering medicines for the rest of your life.

When to take CAVSTAT

- Take CAVSTAT once a day, at about the same time each day. Keeping a regular time for taking CAVSTAT will help to remind you to take it.
- CAVSTAT can be taken at any time of the day. It does not matter whether you take CAVSTAT with food or on an empty stomach.

If you forget to take CAVSTAT

- CAVSTAT should be taken regularly at the same time each day. If you forget to take a dose of CAVSTAT, take it as soon as you remember, as long as it is more than 6 hours before your next dose is due. Otherwise, wait until your next dose is due and take it as normal.

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

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

If you take too much CAVSTAT

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

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), 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 CAVSTAT?

Things you should do

Have your blood cholesterol and triglycerides checked when your doctor says so to make sure CAVSTAT is working.

Call your doctor straight away if you:

- become pregnant while you are taking CAVSTAT.

Remind any doctor, dentist or pharmacist you visit that you are taking CAVSTAT.

Things you should not do

- Do not stop taking CAVSTAT unless you have discussed it with your doctor.

Things that may help your condition

- While taking CAVSTAT, you also need to follow a low-fat diet, control your weight and exercise regularly.

Driving or using machines

Be careful before driving a car or operating machinery until you know how CAVSTAT affects you.

CAVSTAT generally does not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, CAVSTAT may cause dizziness in some people.

Drinking alcohol

Tell your doctor if you regularly drink large amounts of alcohol.

Excessive alcohol consumption may not be safe in patients taking CAVSTAT.

Looking after your medicine

- Keep your tablets in the blister pack until it is time to take them.

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

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

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date.

6. Are there any side effects?

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
• headache • constipation • dizziness • nausea (feeling sick) • stomach pain • unusual tiredness or a general feeling of weakness (asthenia) • muscle pain (myalgia) • stiff or painful joints (arthralgia)	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
Metabolism-related • significant increase in your need to urinate or if you are significantly more hungry or thirsty than usual **Muscle-related:** • aching muscles, muscle tenderness or weakness not caused by exercise (including eye muscle, or muscles used when breathing), particularly if you also have a fever or generally feel unwell **Allergic and severe skin reaction-related:** • difficulty breathing, swelling of the face, eyelids or lips • widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome	**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.**

Serious side effects	What to do
• rash on the skin or sores in the mouth **Lung-related:** • difficulty breathing, coughing, particularly if you also feel generally unwell (e.g. fatigue, weight loss, fever)	

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.

Reporting side effects

After you have received medical advice for any side effects you have experienced, 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 CAVSTAT contains

Active ingredient (main ingredient)	rosuvastatin calcium
Other ingredients (inactive ingredients)	All CAVSTAT tablets contain: • lactose monohydrate • microcrystalline cellulose • light magnesium oxide • crospovidone • magnesium stearate • hypromellose • triacetin. • Titanium dioxide The 5 mg tablets also contain Iron oxide yellow. The 10 mg and 20 mg also contain iron oxide red, quinoline yellow aluminum lake, and brilliant blue FCF aluminum lake. The 40 mg tablets also contain sunset yellow FCF aluminum lake, allura red AC aluminum lake, and brilliant blue FCF aluminum lake.
Potential allergens	lactose monohydrate

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

What CAVSTAT looks like

CAVSTAT 5 mg are yellow, round, film-coated, biconvex tablets debossed “5” on one side and "R" on the other side on one side (Blister pack AUST R 234543, Bottle AUST R 235277).

CAVSTAT 10 mg are pink, round, film-coated, biconvex tablets debossed “10” on one side and "R" on the other side. (Blister pack AUST R 234485, Bottle AUST R 234548).

CAVSTAT 20 mg are pink, round, film-coated, biconvex tablets debossed “20” on one side and "R" on the other side. (Blister pack AUST R 234514, Bottle AUST R 234476).

CAVSTAT 40 mg are pink, oval, film-coated, biconvex tablets debossed “5” on one side and "R" on the other side. (Blister pack AUST R 234508, Bottle AUST R 234461).

CAVSTAT tablets 5 mg, 10 mg, 20 mg and 40 mg are available in blister packs in cartons of 30 tablets, and are also available in bottles of 30 and 90 tablets.

Some strengths, pack sizes and/or pack types may not be marketed.

Who sponsors CAVSTAT

Accord Healthcare Pty Ltd

Level 24, 570 Bourke Street

Melbourne Victoria 3000

Australia

Who distributes CAVSTAT

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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