

TROVAS

Atorvastatin Calcium 10/20/40/80 mg Tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about TROVAS.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

This leaflet was last updated on the date at the end of this leaflet. More recent information may be available. The latest Consumer Medicine Information is available from <https://www.ebs.tga.gov.au/> and may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking TROVAS against the benefits it is expected to 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 TROVAS is used for

TROVAS is used to lower high cholesterol levels in your blood.

TROVAS also helps reduce the risk of having a heart attack or stroke in people who have high blood pressure and coronary heart disease (CHD) or who have multiple risk factors for CHD, including diabetes, a history of stroke, or small blood vessel disease.

Cholesterol is a type of blood fat needed by the body for many things, such as building cell lining, 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 its level may become 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 'bad' cholesterol in your blood, it may begin to '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 patches called plaque 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 are different types of cholesterol. LDL-C, or low-density-lipoprotein cholesterol, is the 'bad' cholesterol that can block your blood vessels. HDL-C, or high-density-lipoprotein cholesterol, is the 'good' cholesterol that is thought to remove the bad cholesterol from the blood vessels.

There is another type of blood fat called triglyceride, which is a source of energy. High levels of triglyceride and a low level of 'good' cholesterol may increase the risk of heart disease.

In some patients, atorvastatin is used to treat high levels of 'bad' cholesterol and high levels of triglyceride together.

The symptoms of high cholesterol and triglycerides are usually not noticeable, but your doctor can measure their levels with a simple blood test.

How TROVAS works

TROVAS contains atorvastatin, which belongs to a group of medicines called HMG-CoA reductase inhibitors. It works by reducing the amount of 'bad' cholesterol made by the liver and also raises the level of the 'good' cholesterol. TROVAS also helps to reduce the risk of a heart attack or stroke.

To get the best results, you also need to follow a low-fat diet. Your doctor may suggest other ways to help control your condition, including regular exercise, weight control and quitting smoking.

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

Treatment with TROVAS does not lessen the need to control other risk factors for CHD, such as high blood pressure, high blood sugar (diabetes) and smoking. Therefore it is important to follow the lifestyle changes recommended by your doctor.

Ask your doctor if you want more information about why TROVAS has been prescribed for you.

Your doctor may have prescribed TROVAS for another reason.

TROVAS is not addictive. It is available only with a doctor's prescription.

Before you take TROVAS

When you must not take TROVAS

Do not take TROVAS if:

- You have or have ever had an allergy to atorvastatin or any of the ingredients of TROVAS listed at the end of this leaflet. Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty in breathing, swelling of the face, lips, tongue or other parts of the body, rash, itching or hives on the skin.
- You have active liver disease.
- 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.
- Atorvastatin may affect your developing baby if you take it during pregnancy.
- You are breast-feeding or intend to breast-feed. Atorvastatin passes into breast milk and may affect your baby.
- You are taking the antibiotic fusidic acid which is used to treat infections.
- You are taking the antivirals, glecaprevir/pibetasvir for the treatment of Hepatitis C

TROVAS contains lactose. If you have intolerance to some sugars, contact your doctor before taking TROVAS.

Do not take if the packaging is torn or shows signs of tampering.

Do not take this medicine after the expiry date printed on the pack.

If you take this medicine after the expiry date has passed, it may not work as well. If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether to start taking TROVAS, talk to your doctor.

Before you start to take it

Before starting treatment with TROVAS, your doctor will test your liver function. You will also need to get these tests done regularly while you are taking TROVAS.

Tell your doctor if:

- You have any allergy to any other medicines or any other substances, such as foods, preservatives or dyes
- You have problem(s) with your liver or kidney(s)
- You have had a type of stroke called a haemorrhagic stroke or a type of stroke called a lacunar stroke. This medicine may increase the risk of you having another haemorrhagic stroke.
- You have unexplained/persistent muscle pain, weakness or tenderness from other medicines used to treat high cholesterol or triglycerides.
- You have breathing problems.

If you have not told your doctor about any of the above, tell him/her before you take any TROVAS.

Taking other medicines

Tell your doctor if you are taking any other medicines, including all prescription medicines, all medicines, vitamins, herbal supplements or natural therapies you buy without a prescription from a pharmacy, supermarket, naturopath or health food shop.

Some medicines may interfere with how TROVAS works. These include:

- Digoxin, a medicine used to treat some heart problems
- The antibiotics erythromycin, clarithromycin, rifampicin or fusidic acid
- Phenytoin, a medicine used to treat epilepsy (seizures)
- Oral contraceptive pills for birth control
- Other medicines used to lower cholesterol or triglyceride
- Cyclosporin, a medicine used to suppress the immune system
- Some medicines used to treat some fungal infections, such as itraconazole or 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
- Iletmovir
- Diltiazem, a medicine used to treat angina
- Antacids, medicines used to treat reflux or ulcers
- 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

Excessive grapefruit juice consumption (over 1.2 litres) may result in increased plasma concentrations of atorvastatin causing side effects.

These medicines may be affected by TROVAS 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 will advise you.

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

How to take TROVAS

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

These instructions may differ from the information contained in this leaflet.

Your doctor will discuss with you the need to be on a diet while you are taking TROVAS.

Follow your agreed diet plan carefully.

If you do not understand the directions on the label, ask your doctor or pharmacist for help.

How much to take

Take TROVAS exactly as your doctor has prescribed. The usual dose of TROVAS is between 10-80 mg taken once a day.

How to take it

Swallow TROVAS whole with a glass of water. Do not crush or chew the tablets. If the tablets are chewed or crushed they will not work properly.

TROVAS can be taken with food or on an empty stomach.

When to take it

Take TROVAS at about the same time each day.

Taking your tablet(s) at the same time each day will have the best effect. It will also help you remember when to take them.

How long to take it

TROVAS helps lower your cholesterol. It does not cure your condition. You may have to take

cholesterol-lowering medicine for the rest of your life.

You must continue to take TROVAS for as long as your doctor directs, even if you feel well.

If you stop taking it, your cholesterol may rise again.

If you forget to take it

If 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 medicines as you would normally.

If you are not sure what to do, ask your doctor or pharmacist.

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

This may increase the chances of your getting unwanted side effect(s).

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

Taking too much (overdose)

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

You may need urgent medical attention. Keep telephone numbers of these facilities handy.

While you are taking TROVAS

Things you must do

Keep all of your doctor's appointments so that your progress can be checked.

Have your liver function tested by your doctor before you start taking TROVAS and while you are taking it.

Your cholesterol, triglyceride levels and your liver function tests need to be checked regularly while you are taking this medicine. This will allow you and your doctor to see if TROVAS is helping you to reach your target levels of cholesterol and to avoid some possible side effects.

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, much as atorvastatin.

Have your blood fats checked when your doctor says to.

This is to make sure that TROVAS is helping you to reach the desired levels of cholesterol or triglyceride.

If you become pregnant while you are taking TROVAS, stop taking it and tell your doctor immediately.

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

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

Things you must not do

Do not give TROVAS to anyone else, even if they have the same condition as you.

Do not use TROVAS to treat any other complaints unless your doctor tells you to.

Things to be careful of

Avoid drinking large quantities of alcohol.

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

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

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

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

Avoid eating large quantities of grapefruit or drinking large quantities (over 1.2 litres) of grapefruit juice.

Grapefruit contains one or more substances which change how the body processes some medicines, including atorvastatin.

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

Things you must do

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

- **Weight:** While you are taking TROVAS, 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.
- **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.

- **Smoking:** Smoking increases the risk of you suffering from heart problems. Your doctor may 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 TROVAS.

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.

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

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

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

- muscle and joint pain, muscle weakness
- constipation, diarrhoea
- stomach or belly pain, nausea (feeling sick)
- headache
- urine infection
- heartburn, indigestion or wind
- nose bleeds
- rash
- stuffy or runny nose

These side effects are more common and are usually mild and short-lived.

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

- 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

These are serious side effects that may require medical attention. Serious side effects are rare.

If you notice any of the following, stop taking TROVAS and tell your doctor immediately or go to casualty at your nearest hospital:

- symptoms of allergy such as skin rash, itching, swelling of the face, lips, mouth, tongue, throat or neck which may cause difficulty in swallowing and breathing
- severe blisters and bleeding of the lips, eyes, mouth, nose or genitals
- chest pain
- unexpected muscle pain, tenderness or weakness not caused by exercise, particularly if you also feel unwell with or without 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

These may be serious side effects. You may need urgent medical attention. Serious side effects are rare.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell.

Ask your doctor or pharmacist if you don't understand anything in this list.

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

After taking TROVAS

Storage

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

If you take TROVAS out of the blister pack it will not keep as well.

Keep TROVAS in a cool, dry place where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom or near a sink. Do not leave it in the car or on a window sill.

Heat and dampness can destroy some medicines.

Keep TROVAS where young children cannot reach them.

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 TROVAS or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets you have left over.

Product description

What TROVAS looks like

TROVAS 10 mg tablets are white to off-white, elliptical, film-coated tablets debossed with 'AS10' on one side and plain on the other side.

TROVAS 20 mg tablets are white to off-white, elliptical, film-coated tablets debossed with 'AS20' on one side and plain on the other side.

TROVAS 40 mg tablets are white to off-white, elliptical, film-coated tablets debossed with 'AS40' on one side and plain on the other side.

TROVAS 80 mg tablets are white to off-white, elliptical, film-coated tablets debossed with 'AS80' on one side and plain on the other side.

TROVAS tablets are available in blister packs of 30 tablets and bottles of 30 and 100 tablets.

Ingredients

Active ingredient:

TROVAS 10 mg tablets - atorvastatin calcium equivalent to 10 mg of atorvastatin

TROVAS 20 mg tablets - atorvastatin calcium equivalent to 20 mg of atorvastatin

TROVAS 40 mg tablets - atorvastatin calcium equivalent to 40 mg of atorvastatin

TROVAS 80 mg tablets - atorvastatin calcium equivalent to 80 mg of atorvastatin

Inactive ingredients:

Lactose monohydrate, microcrystalline cellulose, calcium carbonate, croscarmellose sodium, hyrolose, polysorbate 80, magnesium stearate, Opadry White YS-1-7040 (PI 2695) and Antifoam AF Emulsion Q7-2587. In addition the 10, 20 and 40 mg tablets contain Euphorbia antisiphilitica leaf wax.

TROVAS tablets do not contain gluten, sucrose or glucose.

Sponsor

Sun Pharma ANZ Pty Ltd.
Macquarie Park NSW 2113
Australia

Australian Registration Numbers

TROVAS 10 mg tablets: AUST R 179844 (bottles); AUST R 179846 (blisters)

TROVAS 20 mg tablets: AUST R 179834 (bottles); AUST R 179829 (blisters)

TROVAS 40 mg tablets: AUST R 179860 (bottles); AUST R 179840 (blisters)

TROVAS 80 mg tablets: AUST R 179821 (bottles); AUST R 179847 (blisters)

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