

ATORVASTATIN SZ

atorvastatin calcium trihydrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ATORVASTATIN SZ.

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 ATORVASTATIN SZ 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 ATORVASTATIN SZ is used for

ATORVASTATIN SZ is used to lower high cholesterol levels in your blood.

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

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 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.

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.

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 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, atorvastatin is used to treat high cholesterol and high levels of triglyceride 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.

How ATORVASTATIN SZ works

ATORVASTATIN SZ belongs to a group of medicines called HMG-CoA reductase inhibitors. It works by reducing the amount of cholesterol made by the liver. ATORVASTATIN SZ reduces the 'bad' cholesterol and can raise the 'good' cholesterol. ATORVASTATIN SZ also helps to reduce the risk of a heart attack or stroke.

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

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

Your doctor may have prescribed ATORVASTATIN SZ for another reason.

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

Before you take ATORVASTATIN SZ

When you must not take ATORVASTATIN SZ

Do not take ATORVASTATIN SZ if:

- You have or have ever had an allergy to atorvastatin or any of the ingredients of ATORVASTATIN SZ 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/pibrentasvir for the treatment of Hepatitis C.

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

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 ATORVASTATIN SZ, talk to your doctor.

Before you start to take it

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

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 muscle pain, tenderness or weakness from other medicines used to treat high cholesterol or triglyceride.
- **You drink alcohol regularly**
- 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 breathing problems.

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

Taking other medicines

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

Some medicines may interfere with how ATORVASTATIN SZ works. These include:

- Digoxin, a medicine used to treat some heart problems
- Erythromycin, clarithromycin, rifampicin and fusidic acid (antibiotics used to treat infections)

- Phenytoin (used to treat epilepsy or seizures)
- Oral contraceptive pills for birth control
- Other medicines used to lower cholesterol or triglyceride
- Cyclosporin (used to suppress the immune system)
- Itraconazole, ketoconazole (used to treat fungal infections)
- 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
- Letemovir
- Diltiazem (used in the treatment of angina)
- Antacids, medicines used to treat reflux or ulcers
- Spironolactone (used to treat high blood pressure and certain types of swelling)
- Vitamin B3
- Colchicine (used to treat a disease with painful, swollen joints caused by uric acid crystals).

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

How to take ATORVASTATIN SZ

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 ATORVASTATIN SZ.

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

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 other medicines.

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

How to take it

Swallow ATORVASTATIN SZ 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.

ATORVASTATIN SZ can be taken with food or on an empty stomach.

When to take it

ATORVASTATIN SZ can be taken at any time of the day. However, your dose of ATORVASTATIN SZ should be taken 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

Take ATORVASTATIN SZ every day and continue to take it for as long as your doctor tells you.

ATORVASTATIN SZ helps lower your cholesterol. It does not cure your condition. It is important to keep taking your medicine 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 pharmacist for some hints.

If you take 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

ATORVASTATIN SZ. 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 ATORVASTATIN SZ

Things you must 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 ATORVASTATIN SZ 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 ATORVASTATIN SZ.

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

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking ATORVASTATIN SZ.

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

Things you must not do

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

Do not use ATORVASTATIN SZ 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 ATORVASTATIN SZ causing liver problems.

Be careful driving or operating machinery until you know how ATORVASTATIN SZ 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 components that alter the metabolism of some medicines, including atorvastatin. Drinking larger quantities of grapefruit juice (over 1.2 litres) each day while

taking atorvastatin increases your chance of getting side effects.

Things that would be helpful for your condition

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 ATORVASTATIN SZ, 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 ATORVASTATIN SZ.

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 if you notice any of the following and they worry you:

- 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 or difficulty getting up from a fall
- constipation, diarrhoea
- unusual tiredness or weakness
- stomach or belly pain, nausea (feeling sick)
- headache
- heartburn, indigestion or wind
- urine infection
- 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...

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

- yellowing of 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. You may need urgent medical attention. Some serious side effects are rare.

Go to hospital if...

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

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

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

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 ATORVASTATIN SZ

Storage

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

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

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

Protect from light.

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

Product description

What ATORVASTATIN SZ looks like

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

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

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

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

ATORVASTATIN SZ tablets are available in blister packs of 30 tablets.

Ingredients

Active ingredient:

ATORVASTATIN SZ 10 mg tablets - atorvastatin calcium trihydrate equivalent to 10 mg of atorvastatin

ATORVASTATIN SZ 20 mg tablets - atorvastatin calcium trihydrate equivalent to 20 mg of atorvastatin

ATORVASTATIN SZ 40 mg tablets - atorvastatin calcium trihydrate equivalent to 40 mg of atorvastatin

ATORVASTATIN SZ 80 mg tablets - atorvastatin calcium trihydrate equivalent to 80 mg of atorvastatin

Inactive ingredients:

Lactose monohydrate, microcrystalline cellulose, calcium carbonate, croscarmellose sodium, hydroxypropylcellulose, polysorbate 80, magnesium stearate, hypromellose, Macrogol 8000, titanium dioxide, purified talc and Antifoam AF Emulsion Q7-2587. In addition the 10, 20 and 40 mg tablets contain Euphorbia antisyphilitica leaf wax.

ATORVASTATIN SZ tablets do not contain gluten, sucrose or glucose. Contains lactose, milk or milk products.

Supplier

Sandoz Pty Ltd
54 Waterloo Road
Macquarie Park, NSW 2113
Australia
Tel: 1800 726 369

This leaflet was revised in April 2021.

Australian Register Numbers

ATORVASTATIN SZ 10 mg tablets: AUST R 179845 (blisters)

ATORVASTATIN SZ 20 mg tablets: AUST R 179842 (blisters)

ATORVASTATIN SZ 40 mg tablets: AUST R 179823 (blisters)

ATORVASTATIN SZ 80 mg tablets: AUST R 179833 (blisters)