

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

This leaflet answers some common questions about APO-Atorvastatin. 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 this medicine 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 this medicine is used for

The name of your medicine is APO-Atorvastatin. It contains the active ingredient atorvastatin. Atorvastatin lowers high cholesterol levels. It 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, this medicine is used to reduce the risk of having a heart attack or stroke.

What is Cholesterol?

Everyone has cholesterol in their blood. It is a type of 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 take 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 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 '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 areas, also called plaque, 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 several types of blood vessel disease, heart attack, angina and stroke.

There is another type of 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, APO-Atorvastatin is used to treat high cholesterol and high triglycerides together.

How it works

APO-Atorvastatin belongs to a group of medicines called HMG-CoA reductase inhibitors. It works by reducing the amount of cholesterol made by the liver. This medicine reduces the 'bad' cholesterol and raises the 'good' cholesterol. It also helps to protect you from a heart attack or stroke.

When you are taking APO-Atorvastatin, 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 abnormal cholesterol or triglyceride levels. Your doctor can measure your levels with a simple blood test.

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

Your doctor may have prescribed it for another reason.

This medicine is/is not addictive.

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

This medicine is not expected to affect your ability to drive a car or operate machinery.

Before you take this medicine

When you must not take it

Do not take APO-Atorvastatin if:

- **You are pregnant or intend to become pregnant.**
Women of child-bearing age who are taking the medicine should use a proven method of birth control to avoid pregnancy.
The medicine may affect your unborn developing baby if you take it during pregnancy.
- **You are breast-feeding or intend to breast-feed.**
The medicine may pass into breast milk and affect your baby.
- **You have active liver disease or have experienced persistent elevations of serum transaminases (liver blood test results).**
- **You are taking the antibiotic fusidic acid, which is used to treat infections.**
- **You are hypersensitive to, or have had an allergic reaction to, atorvastatin or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hayfever-like symptoms.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

- **The packaging is torn or shows signs of tampering.**
- **The expiry date (EXP) on the pack has passed.**

If you take this medicine after the expiry date has passed, it may not work, or it may make you unwell.

If you are not sure whether to start taking APO-Atorvastatin, 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:

- liver problems

- kidney problems
- muscle pain, tenderness or weakness from other medicines used to treat cholesterol or triglycerides
- a type of stroke called haemorrhagic stroke or a lacunar stroke. If you have had one of these before, this medicine may increase the risk of you having a haemorrhagic stroke.
- breathing problems.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

Do not take this medicine whilst you are pregnant or breastfeeding.

Tell your doctor if you drink alcohol regularly.

If you have not told your doctor about any of the above, tell him/ her before you start taking this medicine.

Taking other medicines

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

Some medicines and this one may interfere with each other. These include:

- digoxin, a medicine used to treat some heart problems
- erythromycin, clarithromycin, rifampicin and fusidic acid which are antibiotics
- phenytoin, a medicine used to treat epilepsy
- oral contraceptives
- 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
- some medicines used to treat fungal infections, such as ketoconazole or itraconazole
- medicines for the treatment of HIV infection such as efavirenz, fosamprenavir, ritonavir, tipranavir, lopinavir saquinavir and darunavir
- medicines for the treatment of Hepatitis C, such as boceprevir and telaprevir
- 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 a disease with painful, swollen joints caused by uric acid crystals.

These medicines may be affected by APO-Atorvastatin 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 and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take this medicine

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

They may differ from the information contained in this leaflet.

Take APO-Atorvastatin only when prescribed by your doctor.

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

How much to take

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

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

How to take it

Swallow the tablet(s) whole with a glass of water. Do not chew or crush the tablets.

When to take it

APO-Atorvastatin can be taken at any time of the day. However, your dose of APO-Atorvastatin 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 the tablet(s).

APO-Atorvastatin can be taken with or without food.

How long to take it

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

APO-Atorvastatin helps to lower your levels of cholesterol, but it does not cure your condition. Therefore, you must continue to take it as directed by your doctor.

If you forget to take it

If it is almost time to take 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 experiencing 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 (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and

Emergency at the nearest hospital, if you think that you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using this medicine

Things you must do

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

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 this medicine, stop taking it 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.

Have your cholesterol and triglyceride levels checked when your doctor says, to make sure that is working.

Your doctor will ask you to have your liver function tested from time to time while you are taking APO-Atorvastatin to make sure the medicine is working and to prevent side effects. Your cholesterol and triglyceride levels also need to be checked regularly while you are taking this medicine.

Things you must not do

Do not take this medicine 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.

Things to be careful of

Avoid drinking large quantities of alcohol.

Drinking large quantities of alcohol may increase your chance of APO-Atorvastatin 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 APO-Atorvastatin.

Drinking very large quantities (over 1.2 litres) of grapefruit juice each day increases your chance of this medicine causing side effects.

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

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

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

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking this medicine.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

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

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 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 pain, nausea (feeling sick)
- heartburn, indigestion or wind
- urine infection
- headache
- stuffy or runny nose
- nose bleeds
- rash

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:

- 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.

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

If any of the following happen, stop taking your medicine and tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- symptoms of an allergic reaction including cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash itching, hives on the skin; fainting or hayfever-like symptoms
- 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.

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.

Storage and Disposal

Storage

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

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

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

Protect from light.

Do not store this medicine 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

APO-Atorvastatin 10 mg tablets are white to off-white, elliptical, film-coated tablets debossed "AS10" on one side and plain on the other side. AUST R 286636, 179854

APO-Atorvastatin 20 mg tablets are white to off-white, elliptical, film-coated tablets debossed

"AS20" on one side and plain on the other side.

AUST R 286637, 179822

APO-Atorvastatin 40 mg tablets are white to off-white, elliptical, film-coated tablets debossed "AS40" on one side and plain on the other side.

AUST R 286638, 179857

APO-Atorvastatin 80 mg tablets are white to off-white, elliptical, film-coated tablets debossed "AS80" on one side and plain on the other side.

AUST R 286639, 179852

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

Ingredients

The active ingredient of APO-Atorvastatin is atorvastatin (as calcium trihydrate).

This medicine also contains the following:

- calcium carbonate
- croscarmellose sodium
- lactose monohydrate
- microcrystalline cellulose
- magnesium stearate
- Polysorbate 80
- Opadry YS-1-7040 White (ARTG 2695)
- hyprolose
- anti-foam emulsion Q7-2587 (ARTG 1515)
- Candelilla Wax (only for 10, 20 and 40 mg)

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

Apotex Pty Ltd
16 Giffnock Avenue
Macquarie Park NSW 2113
Australia

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This leaflet was prepared in December 2018.