

APO-Atorvastatin

Contains the active ingredient, atorvastatin calcium trihydrate

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.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits he/she expects it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

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.

Your doctor may have prescribed this medicine for another reason.

Ask your doctor if you have any questions about why APO-Atorvastatin has been prescribed for you.

There is no evidence that this medicine is addictive.

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 hay fever-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

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - liver problems
 - kidney problems
 - muscle pain, tenderness or weakness from other medicines used to treat cholesterol or triglycerides
 - a type of stroke called a haemorrhagic stroke or 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.
3. You drink alcohol regularly.
4. You are currently pregnant or you plan to become pregnant. Do not

take this medicine whilst pregnant.

5. You are currently breastfeeding or you plan to breast-feed. Do not take this medicine whilst breastfeeding.
6. You are planning to have surgery or an anaesthetic.
7. You are currently receiving or are planning to receive dental treatment.
8. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interfere with APO-Atorvastatin. These include:

- digoxin, a medicine used to treat some heart problems
- the antibiotics erythromycin, clarithromycin and rifampicin and fusidic acid
- phenytoin, a medicine used to treat epilepsy
- oral contraceptives
- other medicines to treat high cholesterol or triglycerides
- antacids, medicines used to treat reflux or ulcers
- cyclosporin, a medicine used to suppress the immune system
- some medicines used to treat some fungal infections, such as itraconazole or ketoconazole
- 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. Your doctor or pharmacist has more information on medicines to be careful with or to avoid while taking APO-Atorvastatin.

How to take this medicine

Follow all directions given to you by your doctor carefully. These directions may differ from the information contained in this leaflet.

Take APO-Atorvastatin only when prescribed by your doctor.

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 for 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 tablet(s) as you would normally.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

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 have trouble remembering to take your tablets, ask your pharmacist for some hints.

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking this medicine

Things you must do

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant. If you become pregnant while you are taking this medicine, stop taking it and contact your doctor immediately.
- you are breastfeeding or are planning to breast-feed

- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

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.

Go to your doctor regularly for a check-up.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor tells you to.
- Stop taking your medicine, or change the dosage, without first 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 APO-Atorvastatin causing side effects.

Be careful driving or operating machinery until you know how APO-Atorvastatin 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.

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking APO-Atorvastatin.

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 to answer any questions you may have.

Tell your doctor if you notice any of the following:

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

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

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

These may be serious side effects and you may need medical attention:

- 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.

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

These are very serious side effects and you may need urgent medical attention or hospitalisation:

- 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.

These may be serious side effects requiring 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.

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

Allergic reactions

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

Symptoms of an allergic reaction may include some or all of the following:

- 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
- hay fever-like symptoms.

Storage and disposal

Storage

Keep your tablets in their original packaging until it is time to take them.

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

Keep it 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 your tablets in the car or on windowsills.

Heat and dampness can destroy some medicines.

Keep your tablets where young children cannot reach them.

A locked cupboard at least one and a half metres off the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking APO-Atorvastatin, or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.

Product description

What APO-Atorvastatin looks like

New Formulation

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.

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.

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.

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. They are available in blister packs of 30 tablets.

Old Formulation

APO-Atorvastatin 10 mg tablets are white, oval, biconvex, film-coated tablets. Engraved "APO" on one side, "A10" on the other side.

APO-Atorvastatin 20 mg tablets are white, oval, biconvex, film-coated tablets. Engraved "APO" on one side, "ATV20" on the other side.

APO-Atorvastatin 40 mg tablets are white, oval, biconvex, film-coated tablets. Engraved "APO" on one side, "ATV40" on the other side.

APO-Atorvastatin 80 mg tablets are white, oval, biconvex, film-coated tablets. Engraved "APO" on one side, "ATV80" on the other side.

They are available in blister packs of 30 tablets.

Also available in bottles of 30 tablets.

Ingredients

New Formulation

Active Ingredient:

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

It also contains the following inactive ingredients:

- Calcium Carbonate
- Croscarmellose sodium
- Lactose monohydrate
- microcrystalline cellulose
- magnesium stearate
- Polysorbate 80 Opadry YS-1-7040 White (ARTG 2695)
- Hyprolose
- Anti foam AF emulsion Q7-2587 (ARTG 1515) Candelilla Wax (Only for 10, 20 and 40 mg)

This medicine is gluten-free, sucrose-free, tartrazine-free and other azo dyes-free.

Old Formulation

Active Ingredient:

The active ingredient of APO-Atorvastatin is atorvastatin (as atorvastatin calcium propylene glycol solvate).

It also contains the following inactive ingredients:

- calcium acetate
- croscarmellose sodium
- sodium carbonate anhydrous
- microcrystalline cellulose
- magnesium stearate
- colloidal anhydrous silica
- hypromellose
- hydroxypropylcellulose
- macrogol 8000
- titanium dioxide
- purified water.

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and other azo dyes-free.

Australian Registration Numbers

New Formulation

APO-Atorvastatin 10 mg tablets (blister pack):
AUST R 286636.

APO-Atorvastatin 20 mg tablets (blister pack):
AUST R 286637.

APO-Atorvastatin 40 mg tablets (blister pack):
AUST R 286638.

APO-Atorvastatin 80 mg tablets (blister pack):
AUST R 286639.

Old Formulation

APO-Atorvastatin 10 mg tablets (blister pack):
AUST R 153718.

APO-Atorvastatin 10 mg tablets (bottle):
AUST R 153727.

APO-Atorvastatin 20 mg tablets (blister pack):
AUST R 153732.

APO-Atorvastatin 20 mg tablets (bottle):
AUST R 153731.

APO-Atorvastatin 40 mg tablets (blister pack):
AUST R 153738.

APO-Atorvastatin 40 mg tablets (bottle):
AUST R 153728.

APO-Atorvastatin 80 mg tablets (blister pack):
AUST R 153729.

APO-Atorvastatin 80 mg tablets (bottle):
AUST R 153730.

Sponsor

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