

# APO-Atorvastatin

*Atorvastatin calcium trihydrate*

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## Consumer Medicine Information

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

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### What is in this leaflet

This leaflet answers some of the more common questions about APO-Atorvastatin. It does not contain all of 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 he/she expects it will have for you.

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

**Keep this leaflet with your medicine.**

You may need to read it again.

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### What this medicine is used for

The name of your medicine is APO-Atorvastatin. It contains the active ingredient atorvastatin.

Atorvastatin is used to lower high cholesterol levels.

It is also used to help reduce the risk of having a heart attack or stroke in people who have high blood pressure and coronary heart disease (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 the 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 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, or low-density lipoprotein, is the 'bad' cholesterol that can block your blood vessels. HDL, 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 areas, also 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 blood stream; 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, APO-Atorvastatin is used to treat high cholesterol and high triglycerides 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 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 can raise the 'good' cholesterol. It also helps to protect you from a heart attack or stroke.

**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 not addictive.

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

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### Before you take this medicine

*When you must not take it*

**Do not take APO-Atorvastatin if you have an allergy to:**

- any medicines containing atorvastatin
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

**Do not take APO-Atorvastatin if you have active liver disease.**

**Do not take this medicine if you are pregnant or intend to become pregnant.**

**If you are a woman of childbearing age and are taking this medicine, use a proven method of birth control to avoid pregnancy.**

The medicine may affect your developing baby if you take it during pregnancy.

**Do not breast-feed if you are taking this medicine.**

The active ingredient in this medicine may pass into breast milk and affect your baby.

**Do not take this medicine if you are taking the antibiotic fusidic acid which is used to treat infections.**

**Do not take this medicine if you are taking the antivirals, glecaprevir/pibrentasvir for the treatment of Hepatitis C.**

**Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether to start taking APO-Atorvastatin, talk to your doctor.

### *Before you start to take it*

Your doctor will ask you to have your liver function tested before you start to take this medicine

**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 high cholesterol or triglycerides
- a type of stroke called a haemorrhagic stroke or a type of stroke called 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.

**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:**

- 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 be affected by APO-Atorvastatin. You may need different amounts of your medicines, or you may need to take different medicines. Your doctor will advise you.

Tell your doctor or pharmacist if you are taking any of the following:

- digoxin, a medicine used to treat some heart problems
- diltiazem, a medicine used to treat angina
- other medicines to treat high cholesterol or triglycerides
- antacids, medicines used to treat reflux or ulcers
- the antibiotics erythromycin, clarithromycin, rifampicin or fusidic acid

- phenytoin, a medicine used to treat epilepsy (seizures)
- oral contraceptives for birth control
- ciclosporin, 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
- letermovir
- 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.

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

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## How to take this medicine

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

These directions 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 APO-Atorvastatin.

**Follow your agreed diet plan carefully.**

**If you do not understand the instructions, 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 any other medicines.

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

### *How to take it*

Swallow the tablet(s) whole with a full 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 it at the same time each day will have the best effect. It will also help you remember when to take it.

APO-Atorvastatin can be taken with or without food.

### *How long to take it*

Take APO-Atorvastatin every day and continue taking it for as long as your doctor tells you.

APO-Atorvastatin helps to lower your levels of cholesterol, but it does not cure your condition. It is important to keep taking your medicine even if you feel well. If you stop taking APO-Atorvastatin, your cholesterol levels 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 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 getting an unwanted side effect.

**If you are not sure what to do, talk to 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 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.

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## **While you are using this medicine**

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### *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 APO-Atorvastatin 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 APO-Atorvastatin.

**If you become pregnant while you are taking APO-Atorvastatin, stop taking it and contact your doctor immediately.**

**If you are about to start on any new medicine, remind your doctor and pharmacist that you are taking APO-Atorvastatin.**

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

### *Things you must not do*

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

**Do not take this medicine 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 while taking APO-Atorvastatin may increase your chance of getting 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 while taking APO-Atorvastatin increases your chance of getting 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.

### *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 APO-Atorvastatin, you need to follow a diet plan agreed with your doctor. This may include measures to lose some weight.
- **Exercise:** regular exercise can help lower cholesterol levels. It is important not to overdo it. Before

commencing 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 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.

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## Side effects

**Tell your doctor or pharmacist 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.

**Do not be alarmed by the list of possible 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 or belly 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.

These are 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 allergy such as skin rash, itching, swelling of the face, lips, mouth tongue, throat or neck which may cause difficulty in swallowing or 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.

**Tell your doctor if you notice anything else that is making you feel unwell.**

Other side effects not listed above may also occur in some people.

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## 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.**

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## 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 (PI 2695)
- hypromellose
- Antifoam emulsion Q7-2587 (PI 1515)
- Candelilla Wax (only for 10 mg, 20 mg and 40 mg tablets)

Contains sugars as lactose.

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

### *Sponsor*

Arrotex Pharmaceuticals Pty Ltd  
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Cremorne VIC 3121  
Australia  
Tel: 1800 195 055

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