

# APO-ATORVASTATIN

## Consumer Medicine Information (CMI) summary

The [full CMI on the next page](#) has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using APO-ATORVASTATIN?

APO-ATORVASTATIN contains the active ingredient atorvastatin. APO-ATORVASTATIN is used to lower high cholesterol levels. APO-ATORVASTATIN 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) or who are at risk of CHD.

For more information, see Section [1. Why am I using APO-ATORVASTATIN?](#) in the full CMI.

### 2. What should I know before I use APO-ATORVASTATIN?

Do not use if you have ever had an allergic reaction to APO-ATORVASTATIN or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use APO-ATORVASTATIN?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with APO-ATORVASTATIN and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use APO-ATORVASTATIN?

- The usual dose of APO-ATORVASTATIN is between 10-80 mg taken once a day.
- Swallow the tablets whole with a full glass of water. Do not chew or crush the tablets.

More instructions can be found in Section [4. How do I use APO-ATORVASTATIN?](#) in the full CMI.

### 5. What should I know while using APO-ATORVASTATIN?

|                                    |  |
|------------------------------------|--|
| <b>Things you should do</b>        | <ul style="list-style-type: none"><li>- Remind any doctor, dentist or pharmacist you visit that you are using APO-ATORVASTATIN.</li><li>- Keep all of your doctor's appointments so that your progress can be checked.</li></ul>   |
| <b>Things you should not do</b>    | <ul style="list-style-type: none"><li>- Do not stop using this medicine suddenly.</li><li>- Do not give APO-ATORVASTATIN to anyone else, even if they have the same condition as you.</li></ul>  |
| <b>Driving or using machines</b>   | <ul style="list-style-type: none"><li>- Be careful driving or operating machinery until you know how APO-ATORVASTATIN affects you.</li><li>- 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.</li></ul> |
| <b>Drinking alcohol</b>            | <ul style="list-style-type: none"><li>- Avoid drinking large quantities of alcohol</li><li>- Drinking large quantities of alcohol while taking APO-ATORVASTATIN may increase your chance of liver problems.</li></ul>  |
| <b>Looking after your medicine</b> | <ul style="list-style-type: none"><li>- Keep APO-ATORVASTATIN in a cool dry place where the temperature stays below 25°C.</li><li>- Keep your tablets where children cannot reach them.</li></ul>  |

For more information, see Section [5. What should I know while using APO-ATORVASTATIN?](#) in the full CMI.

### 6. Are there any 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. 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.

**This is not a complete list of all possible side effects.** For more information, including what to do if you have any side effects,

see Section [6. Are there any side effects?](#) in the full CMI.

# APO-ATORVASTATIN

Active ingredient(s): *atorvastatin (as calcium trihydrate)*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using APO-ATORVASTATIN. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using APO-ATORVASTATIN.**

### Where to find information in this leaflet:

- [1. Why am I using APO-ATORVASTATIN?](#)
- [2. What should I know before I use APO-ATORVASTATIN?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use APO-ATORVASTATIN?](#)
- [5. What should I know while using APO-ATORVASTATIN?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using APO-ATORVASTATIN?

**APO-ATORVASTATIN contains the active ingredient atorvastatin.**

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. APO-ATORVASTATIN reduces the 'bad' cholesterol and can raise the 'good' cholesterol. APO-ATORVASTATIN also helps to protect you from a heart attack or stroke.

APO-ATORVASTATIN is 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) or who are at risk of CHD. Examples of risk factors for CHD include diabetes, a history of stroke, or small blood vessel disease.

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

Your doctor may have prescribed it for another reason.

APO-ATORVASTATIN is not addictive.

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

### 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 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, 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.

## 2. What should I know before I use APO-ATORVASTATIN?

### Warnings

#### Do not use APO-ATORVASTATIN if you:

- are allergic to atorvastatin, or 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.
- Always check the ingredients to make sure you can use this medicine.
- have active liver disease
  - are pregnant or intend to become pregnant
  - are taking the antibiotic fusidic acid hemihydrate which is used to treat infections
  - are taking the antiviral 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.

### **Check with your doctor if you have 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
- vision problems, eye muscle weakness and drooping eyelid
- 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.

Your doctor will ask you to have your liver function tested before you start to take APO-ATORVASTATIN.

Tell your doctor if you drink alcohol regularly.

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### **Pregnancy and breastfeeding**

Do not take this medicine if 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.**

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

**Do not breastfeed if you are taking this medicine.**

The active ingredient in APO-ATORVASTATIN may pass into breast milk and affect your baby.

### **3. What if I am taking other medicines?**

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

Some 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 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 (fats)

- antacids, medicines used to treat reflux or ulcers
- the antibiotics erythromycin, clarithromycin, rifampicin or fusidic acid hemihydrate
- 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 such as daclatasvir and ledipasvir
- letemovir
- 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
- ticagrelor, a medicine used to prevent blood clots.

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

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect APO-ATORVASTATIN.**

## **4. How do I use APO-ATORVASTATIN?**

### **How much to take**

- Follow the instructions provided and use APO-ATORVASTATIN until your doctor tells you to stop.
- 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 10-80 mg taken once a day.

### **When to take APO-ATORVASTATIN**

- 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 to remember when to take it.
- APO-ATORVASTATIN can be taken with or without food.

### **How to take APO-ATORVASTATIN**

- Swallow the tablets whole with a full glass of water. Do not chew or crush the tablets.
- 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 long to take APO-ATORVASTATIN

- 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 use APO-ATORVASTATIN

APO-ATORVASTATIN should be used regularly at the same time each day.

If you miss your dose at the usual time:

- 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 tablet 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 tablets, ask your pharmacist for some hints.

## If you use too much APO-ATORVASTATIN

If you think that you have used too much APO-ATORVASTATIN, you may need urgent medical attention.

### You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. What should I know while using APO-ATORVASTATIN

### Things you should 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 are about to be started on any new medicine, remind your doctor and pharmacist that you are taking APO-ATORVASTATIN.

### Call your doctor straight away if you:

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

Remind any doctor, dentist or pharmacist you visit that you are using APO-ATORVASTATIN.

### Things you should not do

- Do not stop using this medicine suddenly
- Do not give APO-ATORVASTATIN to anyone else, even if they have the same condition as you
- Do not take APO-ATORVASTATIN to treat any other complaints unless your doctor tells you to.

### 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 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.
- reduce 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.
- avoid smoking: Smoking increases the risk of you suffering from heart problems. Your doctor may advise you to stop smoking.

### Driving or using machines

**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.

### Drinking alcohol

Avoid drinking large quantities of alcohol.

Drinking large quantities of alcohol while taking APO-ATORVASTATIN may increase your chance of getting liver

problems.

**Tell your doctor if you drink alcohol regularly.**

### Drinking Grapefruit juice

**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 liters) of grapefruit juice each day while taking APO-ATORVASTATIN increases your chance of getting side effects.

### Looking after your medicine

- Keep your tablets in the blister pack until it is time to take them. If you take the tablets out of the blister pack they may not keep well.
- Keep APO-ATORVASTATIN in a cool dry place where the temperature stays below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where young children cannot reach it.**

A locked cupboard at least one-and-a-half meters above the ground is a good place to store medicines.

### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

| Less serious side effects   | What to do   |
|---|--|
| muscle and joint pain, muscle weakness, especially in the forearms, thighs, hips, shoulders, neck, and back <ul style="list-style-type: none"> <li>• difficulty climbing stairs or standing up from a chair</li> <li>• difficulty lifting arms over the head</li> <li>• falling and difficulty getting up from</li> </ul> | <p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p> <p>These side effects are the more</p> |

|  |  |
|--|--|
| a fall <ul style="list-style-type: none"> <li>• constipation, diarrhoea</li> <li>• stomach or belly pain, nausea (feeling sick)</li> <li>• heartburn, indigestion or wind</li> <li>• urine infection</li> <li>• headache</li> <li>• stuffy or runny nose</li> <li>• nose bleeds</li> <li>• rash</li> </ul> | common side effects of your medicine. They are usually mild and short-lived. |
|--|--|

### Serious side effects

| Serious side effects   | What to do   |
|--|--|
| <p><b>These are serious side effects that may require medical attention. Serious side effects are rare.</b></p> <ul style="list-style-type: none"> <li>• yellowing of the skin and eyes and dark coloured urine</li> <li>• feeling weak and tired, excessively thirsty and passing more urine</li> <li>• problems with breathing, including shortness of breath, persistent cough and fever</li> <li>• vision problems, eye muscle weakness and drooping eyelid.</li> </ul>  | <p><b>Call your doctor straight away if you notice any of these serious side effects.</b></p>  |
| <p><b>The below list includes very serious side effects.</b></p> <p>You may need urgent medical attention or hospitalisation.</p> <ul style="list-style-type: none"> <li>• 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</li> <li>• chest pain</li> <li>• unexpected muscle pain, tenderness or weakness not caused by exercise, particularly if you also feel unwell or have a fever</li> <li>• 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</li> <li>• severe blisters and bleeding of the lips, eyes, mouth, nose or genitals.</li> </ul> | <p><b>Go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.</b></p> |

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

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

### What APO-ATORVASTATIN contains

|   |   |
|---|---|
| <b>Active ingredient (main ingredient)</b>      | Atorvastatin (as calcium trihydrate)  |
| <b>Other ingredients (inactive ingredients)</b> | <ul style="list-style-type: none"><li>• calcium carbonate</li><li>• lactose monohydrate</li><li>• microcrystalline cellulose</li><li>• croscarmellose sodium</li><li>• polysorbate 80</li><li>• hypromellose</li><li>• magnesium stearate</li><li>• opadry white YS-1-7040</li><li>• candilla wax (only for 10mg, 20mg and 40 mg tablets)</li><li>• antifoam emulsion Q7-2587</li></ul> |

This medicine does not contain gluten.

**Do not take this medicine if you are allergic to any of these ingredients.**

### What APO-ATORVASTATIN looks like

APO-ATORVASTATIN tablets are available in four strengths:

- APO-ATORVASTATIN 10 mg - 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 - 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 - 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 - white to off-white, elliptical, film-coated tablets debossed "AS80" on one side and plain on the other side. AUST R 286639, 179852.

APO-ATORVASTATIN comes in blister packs of 30 tablets and bottles of 100

### Who distributes APO-ATORVASTATIN

APO-ATORVASTATIN is supplied in Australia by:

Arrotex Pharmaceuticals Pty Ltd  
15-17 Chapel st,  
Cremorne, VIC 3121  
Tel: 1800 195 055

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