

APO-AMLODIPINE/ATORVASTATIN

5/10, 5/20, 5/40, 5/80, 10/10, 10/20, 10/40 & 10/80 TABLETS

Contains the active ingredients amlodipine (as besylate) and atorvastatin (as calcium propylene glycol solvate)

Consumer Medicine Information

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

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about amlodipine and atorvastatin combination tablets. 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 they expect it will have for you.

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

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is APO-Amlodipine/Atorvastatin, Tablets. It contains the active ingredients amlodipine besylate and atorvastatin calcium propylene glycol solvate.

It is used to:

- treat high blood pressure
- treat high cholesterol
- treat angina (type of chest pain)
- reduce the risk of heart attack or stroke in patients with high blood pressure who have coronary heart disease (CHD) or multiple risk factors for CHD.

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

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

How it works

This medicine contains a combination of amlodipine and atorvastatin.

Amlodipine belongs to a group of medicines called calcium channel blockers. They work by relaxing your blood vessels, making it easier for your heart to pump blood around the body and help increase the supply of blood and oxygen to your heart.

Calcium channel blockers do not change the amount of calcium in your blood or bones.

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

There is no evidence that this medicine is addictive.

Use in children

There is not enough information to recommend the use of this medicine in children.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- **You have active liver disease or your liver function test results are persistently elevated (check with your doctor).**
- **You are taking the antibiotic fusidic acid which is used to treat infections.**
- **You are pregnant or are a female of childbearing age and are not using effective contraception.** Amlodipine and atorvastatin combination tablets may affect your developing baby if it is taken during pregnancy.
- **You are breastfeeding.** Amlodipine and atorvastatin combination tablets may pass into human breast milk.
- **You are hypersensitive to, or have had an allergic reaction to, amlodipine or 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 expiry date (EXP) printed on the pack has passed.**
- **The packaging is torn, shows signs of tampering or it does not look quite right.**

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:
 - heart problems, including heart failure
 - stroke or transient ischaemic attack (known as 'mini stroke') in the last 6 months
 - low blood pressure
 - liver problems
 - kidney problems
 - muscle pain, tenderness or weakness when taking medicines used to treat high cholesterol or triglycerides
 - breathing problems when taking medicines used to treat high cholesterol or triglycerides.
3. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant.
4. You are currently breastfeeding or you plan to breastfeed. Do not take this medicine whilst breastfeeding.
5. You are planning to have surgery or an anaesthetic.
6. You are currently receiving or are planning to receive dental treatment.
7. 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 interact with amlodipine/atorvastatin. These include:

- other medicines used to treat high cholesterol or triglycerides, such as colestipol
- other medicines used to treat high blood pressure
- digoxin, a medicine to treat heart problems
- some antibiotics such as erythromycin, clarithromycin, rifampicin and fusidic acid
- phenytoin, a medicine used to treat epilepsy (seizures)
- oral contraceptives
- cyclosporine, a medicine used to suppress the immune system
- some medicines used to treat fungal infections, such as ketoconazole and itraconazole
- efavirenz and protease inhibitors such as ritonavir, tipranavir and telaprevir, for the treatment of HIV infection and/or hepatitis C
- diltiazem, a medicines used to treat angina
- cimetidine and antacids, medicines used to treat reflux or ulcers
- spironolactone, a medicine used to treat high blood pressure and certain types of swelling
- colchicine, a medicine used to treat a disease with painful swollen joints caused by uric acid crystals
- vitamin B3
- St John's Wort
- grapefruit juice.

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with amlodipine and/or atorvastatin.

How to take this medicine

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

How much to take

Amlodipine and atorvastatin combination tablet is taken once a day. 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.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

How to take it

Swallow the tablet(s) whole with a full glass of water.

Do not chew or crush tablets.

When to take it

Take this medicine at the same time each day. Taking it at the same time each day will have the best effect and will also help you remember when to take it.

It does not matter if you take it before, with or after food.

How long to take it for

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

It is important to keep taking your medicine even if you feel well. If you stop taking amlodipine/atorvastatin your blood pressure and cholesterol levels may rise again.

Make sure you have enough to last over weekends and holidays.

If you forget to take it

If it is less than 12 hours before your next dose, skip the missed dose and take your next dose at the usual time. 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 missed doses.

This may increase the chance of you experiencing side effects.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints to help you remember.

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
- you are breastfeeding or are planning to breastfeed
- you are about to have any blood tests

- you are going to have surgery or an anaesthetic or are going into hospital.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects. 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

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

Amlodipine and atorvastatin combination tablets may cause dizziness or drowsiness in some people and affect alertness.

Avoid drinking large quantities of alcohol, as this may increase the chance of you experiencing liver problems.

Avoid eating large quantities of grapefruit or drinking large quantities of grapefruit juice, as this may increase the chance of you experiencing side effects.

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking amlodipine and atorvastatin combination tablets or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not. Tell your doctor if you notice any of the following:

- swelling of the ankles, feet, face or hands
- muscle and joint pain, muscle weakness
- headache
- flushing
- fast or irregular heart beats
- dizziness
- tiredness or weakness
- drowsiness or sleepiness
- stomach pain or nausea
- constipation, diarrhoea, wind
- heartburn, indigestion or wind
- urine infection or other infections
- stuffy or runny nose
- nose bleeds
- rash.

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:

- symptoms of liver disease such as itching, yellowing of the skin and eyes and dark coloured urine
- feeling weak and tired, excessively thirsty and passing more urine
- dizziness or lightheadedness on standing up from a sitting or lying position

- problems with breathing, including shortness of breath, persistent cough and fever
- eye pain or change in vision
- changes in mood, feeling anxious or nervous
- chest pain associated with exertion (angina) that lasts longer, is more severe or occurs more often
- chest pain.

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:

- unexpected muscle pain, tenderness or weakness not caused by exercise
- tingling in the hands or feet
- changes in heart beat either fast or slow
- 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
- severe upper stomach pain, often with nausea and vomiting.

If you are 65 years old or over, you may be more likely to experience side effects such as swelling of the feet and ankles, muscle cramps and dizziness.

Other side effects not listed above may occur in some patients.

Allergic reactions

If you think you are having an allergic reaction to amlodipine and atorvastatin combination tablets, 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 medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

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

Do not store your 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 this medicine 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 it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Amlodipine/Atorvastatin Tablets looks like

- **5/10mg tablets**
White to off-white, oval, biconvex, coated tablet. Engraved "5/10" on one side, "APO" on the other side.
- **5/20mg tablets**
White to off-white, oval, biconvex, coated tablet. Engraved "5/20" on one side, "APO" on the other side.
- **5/40mg tablets**
White to off-white, oval, biconvex, coated tablet. Engraved "5/40" on one side, "APO" on the other side.
- **5/80mg tablets**
White to off-white, oval, biconvex, coated tablet. Engraved "5/80" on one side, "APO" on the other side.
- **10/10mg tablets**
Light blue, oval, biconvex, coated tablet. Engraved "10/10" on one side, "APO" on the other side.
- **10/20mg tablets**
Light blue, oval, biconvex, coated tablet. Engraved "10/20" on one side, "APO" on the other side.
- **10/40mg tablets**
Light blue, oval, biconvex, coated tablet. Engraved "10/40" on one side, "APO" on the other side.
- **10/80mg tablets**
Light blue, oval, biconvex, coated tablet. Engraved "10/80" on one side, "APO" on the other side.

* Not all strengths, pack types and/or pack sizes may be available.

Ingredients

Each tablet contains 5mg or 10mg of amlodipine (as besylate) and 10mg, 20mg, 40mg or 80mg of atorvastatin (as calcium propylene glycol solvate) as the active ingredients.

It also contains the following inactive ingredients:

- croscarmellose sodium
- microcrystalline cellulose
- iron oxide yellow
- magnesium stearate
- colloidal anhydrous silica
- calcium acetate
- blue colourant (ARTG #10379)
(10mg/10mg, 10mg/20mg, 10mg/40mg and 10mg/80mg strengths only)
- white colourant (ARTG #108944)
(5mg/10mg, 5mg/20mg, 5mg/40mg and 5mg/80mg strengths only).

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

Australian Registration Numbers

- APO-Amlodipine/Atorvastatin 5/10 tablets (blister pack 30):
AUST R 214378.
- APO-Amlodipine/Atorvastatin 5/20 tablets (blister pack 30):
AUST R 214385.

- APO-Amlodipine/Atorvastatin 5/40 tablets (blister pack 30):
AUST R 214375.
- APO-Amlodipine/Atorvastatin 5/80 tablets (blister pack 30):
AUST R 214386.
- APO-Amlodipine/Atorvastatin 10/10 tablets (blister pack 30):
AUST R 214409.
- APO-Amlodipine/Atorvastatin 10/20 tablets (blister pack 30):
AUST R 214360.
- APO-Amlodipine/Atorvastatin 10/40 tablets (blister pack 30):
AUST R 214345.
- APO-Amlodipine/Atorvastatin 10/80 tablets (blister pack 30):
AUST R 214359.

Sponsor

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