

ATORVASTATIN AMNEAL

Atorvastatin calcium film coated tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the more common questions about Atorvastatin AMNEAL.

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 Atorvastatin AMNEAL 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.

What is Atorvastatin AMNEAL used for

Atorvastatin AMNEAL is used to lower high cholesterol levels.

Atorvastatin AMNEAL 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. 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. 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, Atorvastatin AMNEAL 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 Atorvastatin AMNEAL works

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

When you are taking Atorvastatin AMNEAL, you also need to follow a low fat diet. Your doctor may suggest ways to help control your condition such as exercise, weight control and stopping smoking.

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

Atorvastatin AMNEAL is not addictive.

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

Before you start to take Atorvastatin AMNEAL

When you must not take it

Do not take Atorvastatin AMNEAL if:

- you have ever had an allergic reaction to taking Atorvastatin AMNEAL or atorvastatin in the past,
- you have had an allergic reaction to 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 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 unborn developing baby if you take it during pregnancy.

Do not take the medicine if you are breastfeeding or intend to breastfeed.

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 if the packaging is torn or shows signs of tampering.

Do not take this medicine after the expiry date printed on the pack.

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

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

If you are not sure whether to start taking Atorvastatin AMNEAL, 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 Atorvastatin AMNEAL and from time to time while you are taking Atorvastatin AMNEAL.

Tell your doctor if you

- **have had any of the following health or medical problems:**
 - liver problems
 - kidney problems
 - muscle pain, tenderness or weakness from other medicines used to treat high cholesterol or triglycerides.
- **have had a type of stroke called a haemorrhagic stroke or a type of stroke called a lacunar stroke.** This medicine may increase the risk of you having another haemorrhagic stroke
- **breathing problems**
- **drink alcohol regularly**
- **have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes**

If you have not told your doctor about any of the above, tell them before you take any Atorvastatin AMNEAL.

Taking other medicines

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

Some medicines may interfere with Atorvastatin AMNEAL.

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
- oral contraceptives for birth control
- cyclosporin, a medicine used to suppress the immune system
- some medicines used to treat some fungal infections, such as itraconazole
- efavirenz and protease inhibitors for the treatment of HIV infection
- 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
- Hepatitis C protease inhibitors, telaprevir, boceprevir

These medicines may be affected by Atorvastatin AMNEAL, 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 Atorvastatin AMNEAL.

How to take Atorvastatin AMNEAL

Take Atorvastatin AMNEAL exactly as your doctor has prescribed. Follow all directions given to you by your doctor and pharmacist carefully.

These directions may differ from the information contained in this leaflet. If you do not understand the instructions ask your doctor or pharmacist for help.

How much to take

Take Atorvastatin AMNEAL only when prescribed by your doctor. The usual dose of Atorvastatin AMNEAL is between 10–80 mg taken once a day. Swallow Atorvastatin AMNEAL with a full glass of water or other liquid.

When to take it

Atorvastatin AMNEAL can be taken at any time of the day. However, your dose of Atorvastatin AMNEAL should be taken at about the same time each day.

Taking one tablet daily at the same time each day will have the best effect. It will also help you to remember when to take the tablet(s).

Atorvastatin AMNEAL can be taken with or without food.

How long to take it

You must take Atorvastatin AMNEAL every day. Continue taking your medicine for as long as your doctor tells you. Atorvastatin AMNEAL helps to lower your levels of cholesterol, but it does not cure your condition. You may have to take cholesterol-lowering medicine for the rest of your life.

It is important to keep taking your medicine even if you feel well.

If you stop taking Atorvastatin AMNEAL, 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 tablets as you would normally.

If you are not sure what to do, 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 getting an unwanted side effect. If you have trouble remembering to take your tablets, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone the Australian Poisons Information Centre (Ph: 13 11 26) or go to the Accident and Emergency department (Casualty) at your nearest hospital if you think that you or anyone else may have taken too much Atorvastatin AMNEAL.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention. Keep telephone numbers of these facilities handy.

While you are taking Atorvastatin AMNEAL

Things you must do

Have your liver function tested by your doctor before you start taking Atorvastatin AMNEAL and while you are taking it.

Your cholesterol, triglyceride levels and your liver function tests need to be checked regularly while you are taking this medicine.

This will allow you and your doctor to see if Atorvastatin AMNEAL is helping you to reach your target levels of cholesterol **and to avoid some possible side effects.**

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

Tell your doctor or pharmacist that you are taking Atorvastatin AMNEAL if you are about to start on any new medicine.

Things you must not do

Do not give Atorvastatin AMNEAL to anyone else, even if they have the same condition as you.

Do not use Atorvastatin AMNEAL 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 may increase your chance of Atorvastatin AMNEAL causing liver problems.

Avoid eating or drinking large quantities of grape or grapefruit juice.

Grapefruit juice contains one or more components that alter the metabolism of some medicines, including Atorvastatin AMNEAL.

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

Be careful driving or operating machinery until you know how Atorvastatin AMNEAL affects you.

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

If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous if you are not alert.

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 Atorvastatin AMNEAL, 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.
- **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.
- **Smoking:** Smoking increases the risk of you suffering from heart problems. Your doctor may advise you to stop smoking.

Side effects

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

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 or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- muscle and joint pain
- constipation, diarrhoea
- unusual tiredness or weakness
- stomach or belly pain, nausea
- headache
- trouble sleeping
- heartburn, indigestion or wind
- urine infection
- 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:

- 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.

Tell your doctor immediately or go to the casualty department of your nearest hospital if you notice any of the following:

- symptoms of allergy such as skin rash, itching, swelling of the face, lips, mouth throat or neck which may cause difficulty in swallowing and breathing
- 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 very serious side effects requiring urgent medical attention or hospitalisation.

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.

After taking Atorvastatin AMNEAL

Storage

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 Atorvastatin AMNEAL in a cool dry place where the temperature stays below 25°C. Protect from light and moisture.

Do not store Atorvastatin AMNEAL 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 Atorvastatin AMNEAL, or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.

Further information about Atorvastatin AMNEAL

This is not all the information that is available on Atorvastatin AMNEAL. If you have any more questions or are not sure about anything ask your doctor or pharmacist.

Product description

What it looks like

Atorvastatin AMNEAL is available as:

10mg white, oval, biconvex, film-coated tablets.

20mg white, oval, biconvex, film-coated tablets with a breakline on one side.

40mg white, oblong, biconvex,
film-coated tablets.

80mg white, oblong, biconvex,
film-coated tablets with a breakline
on one side.

Atorvastatin AMNEAL 10mg,
20mg, 40mg and 80mg are
available in blister packs of 30
tablets.

Ingredients:

The active ingredient in
Atorvastatin AMNEAL tablets is
atorvastatin (as calcium).
Atorvastatin AMNEAL tablets also
contain the following inactive
ingredients:

- Attapulgitte – activated
- Microcelac 100
- Cellulose – microcrystalline
- Starch pregelatinised maize
- Hydroxypropyl cellulose
- Magnesium stearate
- Silica – colloidal anhydrous
- Opadry II complete film coating
system OY-LS-28908 White
(ARPING 12345) consisting of
Hypromellose, Lactose,
Titanium dioxide and Macrogol
4000.

Supplier

Amneal Pharma Australia Pty Ltd
12 River Street
South Yarra VIC 3141

Australian Registration Numbers

Atorvastatin AMNEAL 10 mg -
AUST R 178535

Atorvastatin AMNEAL 20 mg -
AUST R 178524

Atorvastatin AMNEAL 40 mg -
AUST R 178542

Atorvastatin AMNEAL 80 mg -
AUST R 178525

This leaflet was prepared in March
2016.