

ATORVASTATIN GH

atorvastatin calcium

Consumer Medicine Information

What is in this leaflet

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

It does not contain all 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 GH against the benefits it is expected to have for you.

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

Keep this leaflet with your medicine.

You may need to read it again.

What Atorvastatin GH is used for

Atorvastatin GH is used to lower high cholesterol levels. Atorvastatin GH 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 GH is used to treat high cholesterol and high triglycerides together.

How Atorvastatin GH works

Atorvastatin GH belongs to a group of medicines called HMG-CoA reductase inhibitors. It works by reducing the amount

of cholesterol made by the liver. Atorvastatin GH reduces the 'bad' cholesterol and raises the 'good' cholesterol. Atorvastatin GH also helps to protect you from a heart attack or stroke.

When you are taking Atorvastatin GH, 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.

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

Atorvastatin GH is not addictive.

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

Before you take Atorvastatin GH

When not to take it

Do not take Atorvastatin GH if:

- you have ever had an allergic reaction to taking Atorvastatin GH 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
- you have active liver disease
- you have had muscle pain, tenderness or weakness from other medicines used to treat high cholesterol or triglycerides

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 unborn developing baby if you take it during pregnancy.

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

The medicine may pass into breast milk and affect your baby.

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 GH, 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 GH and from time to time while you are taking Atorvastatin GH.

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

- 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 GH.

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 GH.

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

- digoxin, a medicine used to treat some heart problems
- the antibiotics erythromycin, clarithromycin, rifampicin, or fusidic acid.
- phenytoin, a medicine used to treat epilepsy
- oral contraceptives for birth control
- other medicines to treat high cholesterol or triglycerides
- 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
- diltiazem, a medicine used to treat angina

These medicines may be affected by Atorvastatin GH, 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 GH.

How to take Atorvastatin GH

How much to take

Take Atorvastatin GH only when prescribed by your doctor.

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

Swallow Atorvastatin GH with a full glass of water or other liquid.

How to take it

Take Atorvastatin GH 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.

When to take it

Atorvastatin GH can be taken at any time of the day. However, your dose of Atorvastatin GH 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 GH can be taken with or without food.

How long to take it for

You must take Atorvastatin GH every day. Continue taking your medicine for as long as your doctor tells you.

Atorvastatin GH 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 GH, your cholesterol levels may rise again.

If you take too much

Immediately telephone the Australian Poisons Information Centre (telephone 13 11 26), or the New Zealand National Poisons Information Centre (telephone 0800 POISON or 0800 764 766), 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 GH. 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 GH

Things you must do

Have your liver function tested by your doctor before you start taking Atorvastatin GH 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 GH 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 GH, stop taking it and contact your doctor immediately.

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

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.

Things you must not do

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

Do not use Atorvastatin GH 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 GH 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 GH.

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

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

Atorvastatin GH generally does not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, Atorvastatin GH 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.

Side Effects

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

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

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

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
- tingling in the hands or feet

- dizziness
- ringing in the ears
- pain, infection or bleeding in your nose

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.

How to store Atorvastatin GH

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 GH in a cool dry place where the temperature stays below 25 degrees C. Do not store Atorvastatin GH 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 GH, or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.

Product description

What Atorvastatin GH tablets look like

Atorvastatin GH 10mg film-coated tablets are presented as white, oval, biconvex tablets, with dimensions 10.1±0.1mm x 5.6±0.1mm and 3.7±0.2mm in thickness.

Atorvastatin GH 20mg film-coated tablets are presented as white, oval biconvex tablets, with a breakline on one side and dimensions 12.7±0.1mm x 6.7±0.1mm and 4.6±0.2mm in thickness.

Atorvastatin GH 40mg film-coated tablets are presented as white, oblong, biconvex tablets with dimensions 19.4±0.1mm x 7.8±0.1mm and 4.7±0.2mm in thickness.

Atorvastatin GH 80mg film-coated tablets are presented as white, oblong, biconvex tablets with a breakline on one side and dimensions 22.8±0.1mm, 10.9±0.1mm and 5.7±0.2mm in thickness.

Atorvastatin GH comes in blister packets of 30 tablets.

Ingredients

The active ingredient of Atorvastatin GH is atorvastatin.

The other ingredients are:

- attapulgit – activated
- microcrystalline cellulose
- lactose
- starch – pregelatinised maize
- hydroxypropylcellulose
- magnesium stearate

- opadry II white LS-28908, which contains lactose, hypromellose, Macrogol 4000 and titanium dioxide

Atorvastatin GH tablets contain lactose.

Registration Number

Atorvastatin GH 10mg:

AUST R 180321

Atorvastatin GH 20mg:

AUST R 180320

Atorvastatin GH 40mg:

AUST R 180330

Atorvastatin GH 80mg:

AUST R 180326

Sponsor

Generic Health Pty Ltd
Level 1, 1102 Toorak Road
Camberwell VIC 3124
Australia

Where to go for further information

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

This leaflet was prepared in August 2017.