

LIPITOR(R)

Atorvastatin calcium

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the more common questions about LIPITOR.

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 benefits and risks. Your doctor has weighed the risks of you taking LIPITOR 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 LIPITOR is used for

LIPITOR lowers high cholesterol levels.

LIPITOR is also used in people who have high blood pressure and coronary heart disease (CHD) or who are at risk of CHD (for example, if they have diabetes, a history of stroke, or small blood vessel disease). In these people, LIPITOR is used to reduce the risk of having a heart attack or stroke.

What is cholesterol?

Everyone has cholesterol in their blood. It is a type of fat needed by the body for many things, such as

building cell walls, 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 take 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 is the 'bad' cholesterol that can block your blood vessels. HDL 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 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, LIPITOR is used to

treat high cholesterol and high triglycerides together.

How LIPITOR works

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

When you are taking LIPITOR, you also need to follow a low fat diet and other measures, such as exercise and weight control.

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 LIPITOR for another reason.

Ask your doctor if you have any questions about why LIPITOR has been prescribed for you.

LIPITOR is not addictive.

Before you take LIPITOR

When you must not take it

Do not take LIPITOR if:

- * **you have an allergy to atorvastatin or any of the ingredients listed at the end of this leaflet**

Symptoms of an allergic reaction may include skin rash, itching, difficulty breathing, or swelling of the face.

* **you have active liver disease.**

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

Women of child-bearing age who are taking the medicine should 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 if the expiry date (EXP) on the pack has passed.

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

If you are not sure whether to start taking LIPITOR, talk to your doctor.

Before you start to take it

Tell your doctor if you:

- * **have any other medical conditions including:**
 - liver problems
 - muscle pain, tenderness or weakness from other medicines used to treat cholesterol or triglycerides.
- * **have a history of 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 LIPITOR.

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 LIPITOR. These include:

- * digoxin, a medicine used to treat some heart problems
- * the antibiotics erythromycin, clarithromycin and rifampicin
- * phenytoin, a medicine used to treat epilepsy
- * oral contraceptives
- * 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
- * efavirenz and protease inhibitors for the treatment of HIV infection
- * diltiazem, a medicine used to treat angina.

These medicines may be affected by LIPITOR, 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 LIPITOR.

How to take LIPITOR

How much to take

Take LIPITOR only when prescribed by your doctor.

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

Swallow LIPITOR with a glass of water or other liquid.

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

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

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

LIPITOR can be taken with or without food.

How long to take it

LIPITOR helps to lower your levels of cholesterol, but it does not cure your condition. Therefore, you must continue to take it as directed by your doctor if you expect to lower your cholesterol and keep it down.

You may have to take cholesterol-lowering medicine for the rest of your life. If you stop taking LIPITOR, your cholesterol levels may rise again.

If you forget to take it

If it is almost time for 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(s) as you would normally.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

Do not take a double dose to make up for the dose that you missed.

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 (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 at your nearest hospital if you think that you or anyone else may have taken too much LIPITOR. 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 using LIPITOR

Things you must do

Have your cholesterol and triglyceride levels checked when your doctor says, to make sure that LIPITOR is working.

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

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

Things you must not do

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

Do not use LIPITOR 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 LIPITOR causing liver problems.

Avoid drinking large quantities of grapefruit juice.

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

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

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

LIPITOR generally does not cause any problems with your ability to drive a car or operate machinery.

However, as with many other medicines, LIPITOR may cause dizziness in some people.

Side effects

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

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:

- * constipation, diarrhoea
- * unusual tiredness or weakness
- * stomach or belly pain, nausea
- * headache
- * trouble sleeping.

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:

- * swelling of the face, lips, mouth throat or neck which may cause difficulty in swallowing and breathing
- * unexpected muscle pain, tenderness or weakness not caused by exercise

- * tingling in the hands or feet
- * rash, itching.

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.

After using LIPITOR

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

Further information

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

Product description

What it looks like

LIPITOR tablets are white oval tablets, marked with:

- * 10 mg PD155
- * 20 mg PD156
- * 40 mg PD157
- * 80 mg PD158 (only available in Australia)

LIPITOR comes in blister packets of 30 tablets.

Ingredients

The active ingredient of LIPITOR is atorvastatin.

The inactive ingredients are:

- * calcium carbonate
- * microcrystalline cellulose
- * lactose
- * croscarmellose sodium
- * polysorbate 80
- * hydroxypropylcellulose
- * magnesium stearate
- * opadry white YS-1-7040
- * simethicone emulsion
- * candelilla wax (contained in 10, 20, and 40 mg tablets).

LIPITOR tablets contain lactose.

Distributor

LIPITOR is supplied in Australia by:

Pfizer Australia Pty Ltd
ABN 50 008 422 348
38-42 Wharf Road
West Ryde NSW 2114
Australia

Toll Free Number: 1800 675 229

LIPITOR is supplied in New Zealand by:

Pfizer New Zealand Ltd
PO Box 3998
Auckland, New Zealand

Toll Free Number: 0800 736 363

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Australian Registration Number

10mg AUST R 59603

20mg AUST R 59606

40mg AUST R 59607

80mg AUST R 77326

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