

TORVASTAT®

contains the active ingredient atorvastatin calcium

Consumer Medicine Information

What is in this leaflet

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

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 TORVASTAT 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 TORVASTAT is used for

TORVASTAT is used to lower high cholesterol levels.

TORVASTAT can be 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. Some examples of risk factors for CHD are 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. Low Density Lipoprotein (LDL) is the “bad” cholesterol that can block your blood vessels. High Density Lipoprotein (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. Sometimes the plaque can detach from the vessel wall and float in the bloodstream where it may 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, TORVASTAT 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 TORVASTAT works

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

This medicine is only available with a doctor’s prescription. **Ask your doctor if you have any questions about why TORVASTAT has been prescribed for you. Your doctor may have prescribed TORVASTAT for another reason.**

TORVASTAT is not addictive.

Before you take TORVASTAT

When you must not take it

Do not take TORVASTAT 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:

- 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 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 this 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 TORVASTAT 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 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 TORVASTAT, 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 TORVASTAT.

Tell your doctor if you have any other medical conditions including:

- 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
- have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.

Tell your doctor if you drink alcohol regularly.

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

Taking other medicines

Tell your doctor or pharmacists 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 TORVASTAT. These include:

- digoxin, a medicine used to treat some heart problems
- the antibiotics erythromycin, clarithromycin, rifampicin or fusidic acid
- phenytoin, a medicine used to treat epilepsy (seizures)
- 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 such as itraconazole or ketoconazole
- efavirenz and protease inhibitors for the treatment of HIV infection and/or Hepatitis C
- diltiazem, a medicine used to treat angina
- antacids, medicines to treat reflux or ulcers
- 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.

These medicines may be affected by TORVASTAT, 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 TORVASTAT. Your doctor and pharmacists have more information on medicines to be careful with or avoid while taking TORVASTAT.

How to take TORVASTAT

How much to take

Take TORVASTAT only when prescribed by your doctor. The usual dose of TORVASTAT is between 10-80 mg taken once a day.

Swallow TORVASTAT 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

TORVASTAT can be taken at any time of the day with or without food. You should take your dose of TORVASTAT at about the same time each day.

Taking the 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).

How long to take it

TORVASTAT 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. You may have to take cholesterol-lowering medicine for the rest of your life. If you stop taking TORVASTAT, 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 go to the Accident and Emergency department at your nearest hospital if you think that you or anyone else may have taken too much TORVASTAT. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using TORVASTAT

Do not use TORVASTAT 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 the chance of TORVASTAT 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 TORVASTAT.

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

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

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

other medicines, TORVASTAT may cause dizziness in some people.

If you feel dizzy, do not drive, operate machinery or do anything else that could be dangerous.

Things you must do

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

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

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

Things you must not do

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

Side effects

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

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, muscle weakness
- constipation, diarrhoea
- stomach or belly pain, nausea
- headache
- 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, swelling of the face, lips, mouth, tongue, throat or neck which may cause difficulty in swallowing and breathing
- 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
- chest pain.

These may be very 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 TORVASTAT

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 TORVASTAT in a cool dry place where the temperature stays below 25°C.

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

Product description

What it looks like

10 mg: white oval biconvex tablet with "10" on one side and "A" on reverse.

20 mg: white oval biconvex tablet with "20" on one side and "A" on reverse.

40 mg: white oval biconvex tablet with "40" on one side and "A" on reverse.

TORVASTAT is available in blister and bottle* packs of 30 tablets.

Ingredients

The active ingredient of TORVASTAT is Atorvastatin calcium. The inactive ingredients are:

- mannitol
- microcrystalline cellulose
- crospovidone
- sodium carbonate anhydrous
- povidone
- methionine
- magnesium stearate
- talc -purified
- Opadry 03F28446 White

Manufacturer

Sponsor

Spirit Pharmaceuticals Pty Ltd
117 Harrington Street
The Rocks
Sydney NSW 2000

TORVASTAT is supplied in Australia by:

Aspen Pharma Pty Ltd
34-36 Chandos St
St Leonards NSW 2065

Australian registration numbers:

TORVASTAT 10 mg blister pack -

AUST R 194111

TORVASTAT 20 mg blister pack -

AUST R 194113

TORVASTAT 40 mg blister pack -

AUST R 194115

TORVASTAT 10 mg bottle pack* -

AUST R 194112

TORVASTAT 20 mg bottle pack* -

AUST R 194114

TORVASTAT 40 mg bottle pack* -

AUST R 194116

* Not currently marketed in

Australia

Date of information

19 November 2012

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