

# ATORVASTATIN SZ

Atorvastatin Calcium 10/20/40/80 mg Tablets

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## Consumer Medicine Information

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### What is in this leaflet

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This leaflet answers some common questions about ATORVASTATIN SZ.

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 SZ against the benefits it is expected to have for you.

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

**Keep this leaflet with the medicine.**

You may need to read it again.

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### What ATORVASTATIN SZ is used for

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ATORVASTATIN SZ is used to lower high cholesterol levels in your blood.

ATORVASTATIN SZ also helps reduce the risk of having a heart attack or stroke in people who have high blood pressure and coronary heart disease (CHD) or who have multiple risk factors for CHD, including diabetes, a history of stroke, or small blood vessel disease.

#### *What is cholesterol?*

Cholesterol is a type of blood fat needed by the body for many things, such as building 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 its level may become too high.

High cholesterol is more likely to occur with certain diseases or if you have a family history of high cholesterol.

When you have high levels of 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 patches 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 are different types of cholesterol. LDL-C, or low-density-lipoprotein cholesterol, is the 'bad' cholesterol that can block your blood vessels. HDL-C, or high-density-lipoprotein cholesterol, is the 'good' cholesterol that is thought to remove the bad cholesterol from the blood vessels.

There is another type of blood fat called triglyceride. High levels of triglyceride and a low level of 'good' cholesterol may increase the risk of heart disease.

In some patients, atorvastatin is used to treat high levels of 'bad' cholesterol and high levels of triglyceride together.

The symptoms of high cholesterol and triglycerides are usually not noticeable, but your doctor can measure their levels with a simple blood test.

#### *How ATORVASTATIN SZ works*

ATORVASTATIN SZ contains atorvastatin, which belongs to a group of medicines called HMG-CoA reductase inhibitors. It works by reducing the amount of 'bad' cholesterol made by the liver and also raises the level of the 'good' cholesterol. ATORVASTATIN SZ also helps to reduce the risk of a heart attack or stroke.

**To get the best results, you also need to follow a low-fat diet. Your doctor may suggest other ways to help control your condition, including regular exercise, weight control and quitting smoking.**

**Follow all directions given to you by your doctor carefully.**

They may differ from the information contained in this leaflet.

Treatment with ATORVASTATIN SZ does not lessen the need to control other risk factors for CHD, such as high blood pressure, high blood sugar (diabetes) and smoking. Therefore it is important to follow the lifestyle changes recommended by your doctor.

**Ask your doctor if you want more information about why ATORVASTATIN SZ has been prescribed for you.**

Your doctor may have prescribed ATORVASTATIN SZ for another reason.

ATORVASTATIN SZ is not addictive. It is available only with a doctor's prescription.

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## Before you take ATORVASTATIN SZ

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### *When you must not take ATORVASTATIN SZ*

#### **Do not take ATORVASTATIN SZ if:**

- You have or have ever had an allergy to atorvastatin or any of the ingredients of ATORVASTATIN SZ listed at the end of this leaflet. Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty in 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 triglyceride.
- 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.
- Atorvastatin may affect your developing baby if you take it during pregnancy.
- You are breast-feeding or intend to breast-feed. Atorvastatin passes into breast milk and may affect your baby.
- You are taking the antibiotic fusidic acid which is used to treat infections.

ATORVASTATIN SZ contains lactose. If you have intolerance to some sugars, contact your doctor before taking ATORVASTATIN SZ.

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

#### **If you are not sure whether to start taking ATORVASTATIN SZ, talk to your doctor.**

### *Before you start to take it*

#### **Before starting treatment with ATORVASTATIN SZ, your doctor will test your liver function. You will also need to get these tests done regularly while you are taking ATORVASTATIN SZ.**

#### **Tell your doctor if:**

- You have any allergy to any other medicines or any other substances, such as foods, preservatives or dyes.
- You have problem(s) with your liver or kidney(s).
- You have had any unexplained abnormal test results for liver function.
- You drink alcohol regularly.
- You 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.
- You have unexplained/persistent muscle pain, weakness or tenderness with general feeling of being unwell and fever (rhabdomyolysis). Patients with kidney problem(s) are at higher risk of developing this condition.
- You have breathing problems.

#### **If you have not told your doctor about any of the above, tell him/her before you take any ATORVASTATIN SZ.**

### *Taking other medicines*

#### **Tell your doctor if you are taking any other medicines, including**

#### **any that you buy without a prescription from your pharmacy, supermarket or health food shop.**

Some medicines may interfere with how ATORVASTATIN SZ works. These include:

- Digoxin (used to treat certain heart problems)
- Erythromycin, clarithromycin, azithromycin, rifampicin and fusidic acid (antibiotics used to treat infections)
- Phenytoin (used to treat epilepsy or seizures)
- Oral contraceptive pills for birth control
- Other medicines used to lower cholesterol or triglyceride
- Cyclosporin (used to suppress the immune system)
- Itraconazole, ketoconazole (used to treat fungal infections)
- Protease inhibitors for the treatment of HIV infection and/or Hepatitis C, such as efavirenz, fosamprenavir, ritonavir and boceprevir
- Diltiazem (used in the treatment of high blood pressure and some heart conditions such as angina and irregular heart beat)
- Antacids, medicines used 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.

Excessive grapefruit juice consumption (over 1.2 litres) may result in increased plasma concentrations of atorvastatin causing side effects.

These medicines may be affected by ATORVASTATIN SZ or may affect how well it works. You may need different amounts of your medicines or you may need to take

different medicines. Your doctor will advise you.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking ATORVASTATIN SZ.

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## How to take ATORVASTATIN SZ

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**Follow all directions given to you by your doctor and pharmacist carefully.**

These instructions may differ from the information contained in this leaflet.

Your doctor will discuss with you the need to be on a diet while you are taking ATORVASTATIN SZ.

Follow your agreed diet plan carefully.

If you do not understand the directions on the label, ask your doctor or pharmacist for help.

### *How much to take*

Take ATORVASTATIN SZ exactly as your doctor has prescribed. The usual dose of ATORVASTATIN SZ is between 10-80 mg taken once a day.

### *How to take it*

Swallow ATORVASTATIN SZ whole with a glass of water. Do not crush or chew the tablets. If the tablets are chewed or crushed they will not work properly.

ATORVASTATIN SZ can be taken with food or on an empty stomach.

### *When to take it*

**Take ATORVASTATIN SZ 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 them.

### *How long to take it*

ATORVASTATIN SZ helps lower your cholesterol. It does not cure your condition. You may have to take cholesterol-lowering medicine for the rest of your life.

**You must continue to take ATORVASTATIN SZ for as long as your doctor directs, even if you feel well.**

If you stop taking it, your cholesterol 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 medicines as you would normally.

**If you are not sure what to do, ask your doctor or pharmacist.**

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

This may increase the chances of your getting unwanted side effect(s).

If you have trouble remembering to take your medicine, ask your pharmacists for some hints.

### *Taking too much (overdose)*

**Immediately telephone your doctor or the Poisons Information Centre (13 11 26), or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much ATORVASTATIN SZ. Do this even if there are no signs of discomfort.**

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

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## While you are taking ATORVASTATIN SZ

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### *Things you must do*

**Have your liver function tested by your doctor before you start taking ATORVASTATIN SZ 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 SZ is helping you to reach your target levels of cholesterol and to avoid some possible side effects.**

**Have your blood fats checked when your doctor says to.**

This is to make sure that ATORVASTATIN SZ is helping you to reach the desired levels of cholesterol or triglyceride.

**If you become pregnant while you are taking ATORVASTATIN SZ, stop taking it and tell your doctor immediately.**

**If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking ATORVASTATIN SZ.**

### *Things you must not do*

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

**Do not use ATORVASTATIN SZ 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 SZ causing liver problems.

**Be careful driving or operating machinery until you know how ATORVASTATIN SZ affects you.**

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

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

**Avoid eating large quantities of grapefruit or drinking large quantities (over 1.2 litres) of grapefruit juice.**

Grapefruit contains one or more substances which change how the body processes some medicines, including atorvastatin.

*Things you must do*

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 SZ, 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.

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## Side Effects

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**Tell your doctor or pharmacist as soon as possible if you do not feel**

**well while you are taking ATORVASTATIN SZ.**

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
- unusual tiredness or weakness
- stomach or belly pain, nausea
- headache
- difficulty in sleeping
- heartburn, indigestion or wind
- urine infection
- nose bleeds
- rash
- stuffy or runny nose
- back pain.

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

**If you notice any of the following, stop taking ATORVASTATIN SZ and tell your doctor immediately or go to casualty at your nearest hospital:**

- 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
- severe skin reactions such as blisters, sores or ulceration
- chest pain
- unexpected muscle pain, tenderness or weakness not caused by exercise, with or without fever
- sudden onset of severe abdominal pain associated with nausea (feeling sick) and vomiting (being sick); these may indicate inflammation of the pancreas

- yellowing of skin and whites of eyes with decreased appetite, abdominal pain, unexplained fatigue, dark coloured urine or pale coloured stool; these may indicate liver problems
- unusually severe headache, weakness, numbness in face, arms and legs, dizziness and double vision. These may indicate haemorrhagic stroke.
- tingling in the hands or feet
- dizziness
- ringing in the ears
- pain, infection or bleeding in your nose
- feeling weak and tired, excessively thirsty and passing more urine
- problems with breathing, including shortness of breath, persistent cough and fever.

These may be serious side effects. You may need 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.**

**Ask your doctor or pharmacist if you don't understand anything in this list.**

Do not be alarmed by the list of possible side effects. You may not experience any of them.

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## After taking ATORVASTATIN SZ

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### Storage

**Keep your ATORVASTATIN SZ in the blister pack until it is time to take them.**

If you take ATORVASTATIN SZ out of the blister pack it will not keep as well.

**Keep ATORVASTATIN SZ in a cool, dry place where the temperature stays below 25°C.**

**Protect from light.**

**Do not store it or any other medicine in the bathroom or near a sink. Do not leave it in the car or on a window sill.**

Heat and dampness can destroy some medicines.

**Keep ATORVASTATIN SZ where young children cannot reach them.**

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 ATORVASTATIN SZ or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets you have left over.

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## Product description

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### *What ATORVASTATIN SZ looks like*

ATORVASTATIN SZ 10 mg tablets are white to off-white, elliptical, film-coated tablets debossed with 'AS10' on one side and plain on the other side.

ATORVASTATIN SZ 20 mg tablets are white to off-white, elliptical, film-coated tablets debossed with 'AS20' on one side and plain on the other side.

ATORVASTATIN SZ 40 mg tablets are white to off-white, elliptical, film-coated tablets debossed with 'AS40' on one side and plain on the other side.

ATORVASTATIN SZ 80 mg tablets are white to off-white, elliptical, film-coated tablets debossed with 'AS80' on one side and plain on the other side.

ATORVASTATIN SZ tablets are available in blister packs of 30 tablets.

### *Ingredients*

#### **Active ingredient:**

ATORVASTATIN SZ 10 mg tablets - atorvastatin calcium equivalent to 10 mg of atorvastatin

ATORVASTATIN SZ 20 mg tablets - atorvastatin calcium equivalent to 20 mg of atorvastatin

ATORVASTATIN SZ 40 mg tablets - atorvastatin calcium equivalent to 40 mg of atorvastatin

ATORVASTATIN SZ 80 mg tablets - atorvastatin calcium equivalent to 80 mg of atorvastatin

#### **Inactive ingredients:**

Lactose, microcrystalline cellulose, calcium carbonate, croscarmellose sodium, hydroxypropylcellulose, polysorbate 80, magnesium stearate, hypromellose, Macrogol 8000, titanium dioxide, purified talc and Antifoam AF Emulsion Q7-2587. In addition the 10, 20 and 40 mg tablets contain *Euphorbia antisyphilitica* leaf wax.

ATORVASTATIN SZ tablets do not contain gluten, sucrose or glucose.

### *Supplier*

Sandoz Pty Ltd  
54 Waterloo Road  
Macquarie Park, NSW 2113  
Australia  
Tel: 1800 634 500

This leaflet was revised in December 2015.

### *Australian Register Numbers*

ATORVASTATIN SZ 10 mg tablets: AUST R 179845 (blisters)

ATORVASTATIN SZ 20 mg tablets: AUST R 179842 (blisters)

ATORVASTATIN SZ 40 mg tablets: AUST R 179823 (blisters)

ATORVASTATIN SZ 80 mg tablets: AUST R 179833 (blisters)