

# ATORVASTATIN SANDOZ®

*atorvastatin calcium 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 of the more common questions about Atorvastatin Sandoz.

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 this medicine against the benefits they expect 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.

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### What Atorvastatin Sandoz is used for

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Atorvastatin Sandoz is used to lower high cholesterol levels.

Atorvastatin Sandoz can be 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, Atorvastatin Sandoz is used to help 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, Atorvastatin Sandoz is used to treat high cholesterol and high triglycerides together.

### *How Atorvastatin Sandoz works*

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

**When you are taking Atorvastatin Sandoz, 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 Atorvastatin Sandoz for another reason. Ask your doctor if you have any questions about why Atorvastatin Sandoz has been prescribed for you.

Atorvastatin Sandoz is not addictive.

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## Before you take Atorvastatin Sandoz

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### *When you must not take it*

**Do not take this medicine if you have an allergy to:**

- atorvastatin, the active ingredient, or to any of the other ingredients listed at the end of this leaflet under Product description.

Some 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 or have had liver disease.**

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

It may affect your developing baby if you take it during pregnancy.

**Women of child-bearing age who are taking the medicine should use a proven method of birth control to avoid pregnancy.**

**Do not breastfeed if you are taking this medicine.**

The active ingredient in Atorvastatin Sandoz may pass into breast milk and there is a possibility that your baby may be affected.

**Do not take this medicine if you are taking the antibiotic fusidic acid which is used to treat infections.**

**Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

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

**If you are not sure whether to start taking Atorvastatin Sandoz, 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 this medication.**

**Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.**

**Tell your doctor if you have or have had any of the following medical conditions:**

- liver problems
- kidney problems
- muscle pain, tenderness or weakness from other medicines used to treat cholesterol or triglycerides
- drink alcohol regularly
- a type of stroke called a haemorrhagic stroke or a lacunar stroke. This medicine may increase the risk of you having another haemorrhagic stroke
- breathing problems.

**If you have not told your doctor about any of the above, tell him/her before you start taking Atorvastatin Sandoz.**

### *Taking other medicines*

**Tell your doctor or pharmacist if you are taking any other medicines, including:**

- all prescription medicines
- all medicines, vitamins, herbal supplements or natural therapies you buy without a prescription from your pharmacy, supermarket, naturopath or health food shop.

Some medicines and Atorvastatin Sandoz may interfere with each other. These include:

- digoxin, a medicine used to treat some heart problems
- antacids, medicines used to treat reflux or ulcers
- the antibiotics erythromycin, clarithromycin and rifampicin or fusidic acid
- phenytoin, a medicine used to treat epilepsy (seizures)

- 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 or ketoconazole
- protease inhibitors for the treatment of HIV infection and/or Hepatitis C, such as efavirenz, fosamprenavir, ritonavir and boceprevir
- diltiazem, a medicine used to treat angina
- 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 Atorvastatin Sandoz, 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 and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

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## How to take Atorvastatin Sandoz

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

These directions 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 Sandoz.

Follow your agreed diet plan carefully.

**If you do not understand the instructions ask your doctor or pharmacist for help.**

### *How much to take*

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

### *How to take it*

Swallow Atorvastatin Sandoz with a glass of water or other liquid. Do not chew or crush the tablets.

### *When to take Atorvastatin Sandoz*

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

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

Atorvastatin Sandoz can be taken with or without food.

### *How long to take Atorvastatin Sandoz*

Atorvastatin Sandoz 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 Atorvastatin Sandoz, your cholesterol levels may rise again.

### *If you forget to take it*

Take your dose as soon as you remember, and continue to take it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

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

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

### *If you take too much (overdose)*

**Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26), for advice, 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 Atorvastatin Sandoz. Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

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## While you are taking Atorvastatin Sandoz

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### *Things you must do*

**Keep all of your doctor's appointments so that your progress can be checked.**

Your doctor will ask you to have your liver function tested from time to time while you are taking Atorvastatin Sandoz to make sure the medicine is working and to prevent unwanted side effects.

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

If you become pregnant while you are taking this medicine, tell your doctor immediately.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Atorvastatin Sandoz.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

### *Things you must not do*

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

Do not take Atorvastatin Sandoz 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 Atorvastatin Sandoz 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 Atorvastatin Sandoz. Drinking very large quantities (over 1.2 litres) of grapefruit juice each day increases the chance of Atorvastatin Sandoz causing side effects.

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

Atorvastatin Sandoz generally does not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, Atorvastatin Sandoz may cause dizziness in some people. If you feel dizzy, do not drive, operate machinery or do anything else that could be dangerous.

Your doctor or pharmacist can advise you of some self-help measures with regards to your weight control and exercise regime whilst taking Atorvastatin Sandoz as well as advice on alcohol consumption and smoking habits.

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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 Sandoz.**

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

**Do not be alarmed by the following lists of side effects. You may not experience any of them.**

**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
- heartburn, indigestion or wind
- urine infection
- headache
- nasal problems (such as stuffy/runny nose or nose bleeds)
- rash
- abnormal liver blood tests
- raised blood sugar
- trouble sleeping
- back pain.

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

**If any of the following happen, tell your doctor immediately or go to the Accident and Emergency at your nearest hospital:**

- yellowing of the skin and eyes and dark coloured urine
- problems with breathing including shortness of breath, persistent cough and fever
- 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.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

**Tell your doctor or pharmacist if you notice anything that is making you feel unwell.**

Other side effects not listed above may also occur in some people.

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## After taking Atorvastatin Sandoz

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### Storage

**Keep your medicine in the original container.**

If you take it out of its original container it may not keep well.

**Keep your medicine in a cool dry place where the temperature stays below 25°C.**

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

Heat and dampness can destroy some medicines.

**Keep it where children cannot reach it.**

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 this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that are left over.

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## Product description

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### What it looks like

- Atorvastatin Sandoz 10mg film coated tablets - white to almost white, round, biconvex film-coated tablets, debossed with HLA 10 on one side.
- Atorvastatin Sandoz 20mg film coated tablets - light yellow, round, biconvex film-coated tablets, debossed with HLA 20 on one side.
- Atorvastatin Sandoz 40mg film coated tablets - light yellow, round, biconvex film-coated tablets, debossed with HLA 40 on one side.
- Atorvastatin Sandoz 80mg film coated tablets - light yellow, oval, biconvex film-coated tablets, debossed with HLA 80 on one side.

Atorvastatin Sandoz tablets are available in blister packs of 30.

### Ingredients

#### Active ingredient:

- Atorvastatin Sandoz 10mg - 10mg atorvastatin (as atorvastatin calcium).
- Atorvastatin Sandoz 20mg - 20mg atorvastatin (as atorvastatin calcium).
- Atorvastatin Sandoz 40mg - 40mg atorvastatin (as atorvastatin calcium).
- Atorvastatin Sandoz 80mg - 80mg atorvastatin (as atorvastatin calcium).

#### Inactive ingredients:

- microcrystalline cellulose
- lactose
- croscarmellose sodium
- polysorbate 80
- hydroxypropylcellulose
- magnesium oxide, heavy
- colloidal anhydrous silica
- magnesium stearate
- hypromellose
- titanium dioxide

- macrogol 6000
- purified talc
- iron oxide yellow (contained in 20mg, 40mg and 80mg tablets only).

This medicine does not contain gluten or sucrose.

### *Supplier*

#### **Sandoz Pty Ltd**

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19 Harris Street

Pymont NSW 2009

Tel: 1800 634 500

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#### **Australian Register Numbers**

10mg: AUST R 156055

20mg: AUST R 156051

40mg: AUST R 156058

80mg: AUST R 156057