

Core CMI for Statins (*text in italics is instructional for the CMI writer only*)

[Medicine name][®]

(Include phonetic spelling)

Name of active ingredient (include phonetic spelling)

Note to sponsors: For combination products, e.g. a statin and a cholesterol absorption inhibitor, use the relevant 'Core' CMIs and include relevant information from each document and the product PI. In the case of pregnancy and lactation statements, the more restrictive details should be included.

Consumer Medicine Information (CMI)

What is in this leaflet¹

This leaflet answers some common questions about [Medicine name].

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 using this medicine against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What [Medicine name] is used for

[Medicine name] lowers low-density lipoprotein (LDL) cholesterol (*and triglyceride*) levels. It is used in people whose LDL cholesterol level is too high and when diet alone cannot lower this level adequately. (*OR It is used in people whose LDL cholesterol and triglyceride levels are too high and when diet alone cannot lower these levels adequately.*)

¹ Depending on the length of the CMI, consider using a table of contents (see Third Edition of the Usability Guidelines)

Cholesterol [and triglycerides – optional]

Everyone has cholesterol in their blood. It is a type of blood fat needed by the body for many things, such as making bile acids (which help digest food) and some hormones.

Some people have a family history of high cholesterol.

However, having too much cholesterol in the blood can contribute to the development of heart disease.

Cholesterol is present in many foods and is also made in your body by the liver. If your body does not balance the amount of cholesterol it needs with the amount of cholesterol eaten, then your cholesterol becomes too high.

There are different types of cholesterol, called LDL (low-density lipoprotein) and HDL (high-density lipoprotein). LDL cholesterol 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.

If the product also lowers triglyceride levels, add the following paragraph:

There is another type of fat called triglyceride, which is a source of energy. High levels of triglyceride can be associated with a low level of 'good' cholesterol and may increase your risk of heart disease.

Add 1 of the following paragraphs:

EITHER

When you have high levels of 'bad' cholesterol, the cholesterol may '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, 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 heart disease (such as heart attack or angina), and stroke.

OR

Having high levels of 'bad' cholesterol and triglycerides can be a problem. Over time, this can form hard areas, 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 heart disease (such as heart attack or angina), and stroke.

(All) In most people, there are no signs of high cholesterol [or triglycerides]. Your doctor can measure your cholesterol [and triglycerides] with a simple blood test.

Treating high cholesterol

High cholesterol levels can be treated in two main ways:

The first is lifestyle changes – this includes a low-fat diet, increasing physical exercise and weight management.

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If lifestyle changes do not work, your doctor will prescribe a medicine to help lower your cholesterol levels.

How [Medicine name] works

[Medicine name] belongs to a group of medicines known as HMG-CoA reductase inhibitors. It works by reducing the amount of ‘bad’ cholesterol made by the liver and raises the ‘good’ cholesterol.

Do not give [Medicine name] to a child.

The safety and effectiveness of this medicine have not been established in children.

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

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

It is only available with a doctor’s prescription.

Before you take [Medicine name]**When you must not take it**

Include all Contraindications that appear in the PI (examples below)

Do not take the medicine if you:

- have liver disease
- are allergic to [name of active ingredient] or any of the other 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.
- *(add any other specific reactions listed in the PI).*

Any other contraindications, as per PI (e.g. have muscle pain, tenderness etc; paediatric use; gall bladder disease; renal disease

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

If you are a woman of child-bearing age, make sure you are using a proven method of birth control to avoid pregnancy before starting the use [Medicine name]
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 expiry date printed on the pack has passed.

Do not take 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 you should start taking this medicine, talk to your doctor.

Before you start to take it

Include all relevant information from the Precautions section of the PI (examples below). Do not duplicate any information from the previous section, unless necessary.

Tell your doctor if you:

- have allergies to any other medicines including other lipid lowering agents
- have allergies to any substances, such as foods, preservatives or dyes
- have ever had liver disease
Your doctor will do a blood test to make sure you have no problems with your liver
- have kidney disease [*not atorvastatin*]
- drink alcohol regularly
- have unexplained muscle pain, tenderness or weakness

- *Any other precautions as per the PI.*

If you have not told your doctor or pharmacist about any of the above, tell them before you start using the medicine.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may be affected by [Medicine name] or may affect how well it works. These include:

- digoxin, a medicine used to treat heart problems
- other medicines used to regulate cholesterol and triglyceride levels, such as gemfibrozil, fenofibrate, cholestyramine
- nicotinic acid, a vitamin also known as niacin, which is also used to regulate cholesterol and triglyceride levels
- cyclosporin, a medicine used to suppress the immune system
- some antibiotics, such as erythromycin and clarithromycin (*not pravastatin*)
- some medicines used to treat fungal infections (*not pravastatin*)
- *Other medicines as noted in the PI*

Talk to your doctor if you are not sure whether you should be taking this medicine.

You may need to use different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Your doctor or pharmacist has more information on medicines to be careful with or to avoid taking together with [Medicine name].

Core CMI for Statins (*text in italics is instructional for the CMI writer only*)**How to take
[Medicine name]****How to take it**

Take the medicine only as prescribed by your doctor.

Add information specific to your product. For example: Swallow medicine with a glass of water.

Carefully follow all directions given to you by your doctor and pharmacist.

This may differ from the information contained in this leaflet.

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

How much to take

Add information specific to your product.

How long to take it

Take the medicine for as long as your doctor tells you to.

[Medicine name] helps lower your cholesterol (*and triglycerides*). It does not cure your condition.

Therefore, you must continue to take it as directed by your doctor to keep your cholesterol [*and triglyceride*] levels controlled. If you stop taking the medicine, your cholesterol (*and triglyceride*) levels may become out of control.

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 find it hard to remember how to take the tablets, ask your doctor or pharmacist for help.

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

Immediately telephone your doctor or the Poisons Information Centre (in Australia, telephone 131 126; in New Zealand telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think you or anyone else may have taken too much [Medicine name].

Do this even if there are no signs of discomfort or poisoning.

**While you are taking
[Medicine name]****Things you must do**

Reduce your saturated fat intake and eat plenty of fruit and vegetables.

Doing this will help control your cholesterol (*and triglyceride*) levels, as well as your weight.

Be active by maintaining an exercise program that your doctor or other health professional recommends.

This will also help control your cholesterol levels and weight.

Have your cholesterol (*and triglyceride*) levels checked when your doctor says, to make sure the medicine is working.

Even if you are taking medicines to treat cholesterol and triglyceride levels, it is important to have your levels monitored regularly. Your doctor will then be able to decide if you are taking the correct dose or if you need to take more.

Discuss your cholesterol levels and management plan with your doctor.

If you become pregnant while taking the medicine, stop taking it and tell your doctor.

Tell your doctor or pharmacist if you are taking any other medicines.

If you are about to be started on any new medicine, tell your doctor and pharmacist 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.

Any other instructions, as per PI.

Things to be careful of

Avoid drinking large quantities of alcohol.

Limit your alcohol consumption to 3 standard drinks on any day for men, and 2 standard drinks on any day for women.

Drinking large quantities of alcohol may increase the chance of your medicine causing liver disease.

Avoid drinking large quantities of grapefruit juice (*not fluvastatin or pravastatin*).

The way [Medicine name] works is affected by drinking grapefruit juice. It increases the chance of you getting side effects from the medicine.

Talk to your doctor or pharmacist if you have any concerns.

Include a statement on driving if relevant.

Side effects

Suggested general statements to precede the lists of specific side effects:

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using this medicine.

This medicine may have unwanted side effects in some people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need

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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 to answer any questions you may have.

The side effects listed for a particular product will depend on the PI and the company's disclosure policy.

Take care to include only those symptoms that the consumer can detect and do something about (refer to glossary of plain-English terms available from Medicines Australia or the ASMI website www.asmi.com.au).

The following possible side effect lists are placed in order of increasing urgency of the behaviour required. You may need to include one or more lists, depending on the PI.

If possible, take care not to duplicate side effects in more than one list so the consumer is not confused about the action that is required.

Add side effects in dot points, grouping like symptoms to keep the lists as short as possible.

Tell your doctor if

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- headache
- heartburn, stomach pain or discomfort, nausea (feeling sick)
- diarrhoea or constipation
- *other mild side effects, as per PI.*

The above list includes side effects that are usually mild or only last for a short time (*if consistent with the PI*).

Tell your doctor as soon as possible if

Tell your doctor as soon as possible if you notice any of the following:

- unexplained muscle tenderness or weakness not caused by exercise
- *other side effects, as per PI.*

The above list includes serious side effects that may require medical attention. Serious side effects are rare (*if consistent with frequencies in the PI*).

Go to hospital if

If any of the following happen, go to Accident and Emergency at your nearest hospital:

- swelling of the face, lips, mouth, throat or tongue that may cause difficulty in swallowing or breathing
- bruising more easily than usual
- yellowing of the skin and eyes
- *other side effects as per PI.*

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare (*if consistent with the frequencies in the PI*).

Other side effects

Tell your doctor if you notice anything else that is making you feel unwell.

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

Some side effects can only be found when your doctor does blood, urine or other tests from time to time to check your progress.

After using [Medicine name]

This information will be product specific. Following are some examples from the Usability Guidelines. Choose whichever is appropriate or amend as necessary.

Storage

Do not store [Medicine name] 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 using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

This information will be product specific. Following are some examples from the Usability Guidelines. Choose whichever is appropriate or amend as necessary.

What it looks like

Include colour, markings, any tablet scoring, colour and consistency of liquids, pack sizes, etc.

Ingredients

[Medicine name] contains x mg of [name of active ingredient] as the active ingredient. It also contains:

- *list excipients in dot points*

As appropriate, add:

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Manufacturer/Distributor/Supplier

(use appropriate heading)

[Medicine name] is made/distributed/supplied in Australia by:

Include name and address of sponsor

® = Registered Trademark or
™ = Trademark (*if appropriate*)

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This leaflet was prepared in
month/year.

Include AUST R number(s)

You may want to include a
document code and/or a reference
to the approved PI.

Addendum:

The information in this core CMI for Statin Lipid Lowering Agents has been endorsed by the CMI Content/Quality Assurance Reference Group (QARG) as a guide to writing product specific CMIs.

The core CMI provides the basic information that should be included in CMIs to ensure consistency across products in this therapeutic category.

Any additional lifestyle information, such as information on how to reduce saturated fat content or build up an exercise program, may be included by individual companies at their own discretion, and preferably after testing with consumers.

Following is an example of information that has been suggested:

Reduce your saturated fat intake and eat plenty of vegetables and fruit.

Reducing your saturated fat intake means eating less:

- *fatty meals*
- *full fat dairy products*
- *butter*
- *coconut and palm oils*
- *most take-away foods, and*
- *commercially baked products.*

Doing this will help control your cholesterol and triglyceride levels, as well as your weight.

Be active by maintaining an exercise program that your doctor or other health professional recommends.

It is best to start slowly, progressing to at least 30 minutes of moderate-intensity physical activity on 5 or more days each week. Physical activity can be accumulated in shorter 10-minute bouts. If you have been prescribed anti-angina medicine, carry it with you when being physically active.