

APO-Simvastatin

10 / 20 / 40 / 80 mg

Contains the active ingredient, simvastatin

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about simvastatin. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information

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.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is APO-Simvastatin 10 / 20 / 40 / 80 mg. It contains the active ingredient, simvastatin.

It is used to help lower high cholesterol and triglyceride levels (together with diet and other lifestyle changes).

Simvastatin is used by people who have coronary heart disease (CHD) or who are at high risk of CHD (for example, if they have diabetes, a history of stroke, or other blood vessel disease).

Simvastatin may be used, regardless of cholesterol level to:

- help prolong life by reducing the risk of a heart attack
- reduce the risk of stroke
- reduce the need for surgery to increase blood flow to the heart
- reduce the need for hospitalisation due to angina.

Cholesterol:

Everyone has cholesterol and triglycerides in their blood. They are types of blood fat needed by the body for many things, including building cell walls, making bile acids (which help to digest food) and certain hormones. However, too much cholesterol can be a problem. Your body makes cholesterol, but it also comes from food.

Normally the body balances the cholesterol it makes with the cholesterol it gets from food. This means if more cholesterol comes from food, less is made by the body. However, if you eat a diet high in fat, your body may not keep this balance and your cholesterol levels rise.

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, it 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 blood vessels, making it more difficult for the blood to flow. This blocking of your blood vessels can lead to coronary heart disease (such as heart attack and angina), and stroke.

In people with CHD, simvastatin may slow down the hardening of blood vessels and reduce the risk of developing new plaques.

There are different types of cholesterol, called LDL and HDL cholesterol. LDL cholesterol is the 'bad' cholesterol that can block vessels. HDL cholesterol, on the other hand, is the 'good' cholesterol that is thought to remove the bad cholesterol from the blood vessels.

Triglycerides:

Triglycerides are an energy source for the body. However, as with

cholesterol, too much triglycerides can be a problem.

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

This medicine is available only with a doctor's prescription.

How it works

Simvastatin belongs to a group of medicines known as HMG-CoA reductase inhibitors. It works by reducing the amount of cholesterol made by the liver. In terms of good and bad cholesterol, simvastatin reduces the bad cholesterol and raises the good cholesterol.

Simvastatin does not reduce the cholesterol and triglycerides that come from fat in food. Therefore, when you are taking simvastatin 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 high cholesterol or triglycerides. Your doctor can measure your cholesterol and triglycerides with a simple blood test.

There is no evidence that this medicine is addictive.

Use in children

This medicine is not recommended for use in boys or girls under the age of 10 years, or girls who have not yet started their periods.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- you are pregnant or there is a chance that you could become pregnant (i.e. not using adequate contraception)

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

- you are breast-feeding.
Your baby may absorb this medicine from breast milk and therefore there is a possibility of harm to the baby.
- you have liver disease or unexplained high levels of liver enzymes called serum transaminases
- you have had muscle pain, tenderness or weakness (myopathy) from other medicines used to treat high cholesterol or triglycerides
- it has passed the expiry date (EXP) printed on the pack
- the packaging is torn, shows signs of tampering or it does not look quite right
- you are allergic or intolerant to lactose. These tablets contain lactose
- you have had an allergic reaction to simvastatin 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, throat or other parts of the body, itching or hives on the skin.

If you think you are having an allergic reaction, contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:

- liver disease. Your doctor will do a blood test to make sure you have no problems with your liver.
 - kidney disease, thyroid problems or any other medical problems
 - you drink alcohol regularly.
3. You are currently pregnant or breastfeeding or you plan to become pregnant or breast-feed, or there is a chance that you could become pregnant.

Simvastatin must not be used during pregnancy or while breast-feeding, or if there is a possibility of pregnancy.

4. You have recently been vaccinated or plan to get a vaccination.
5. You are planning to have surgery.
6. You are currently receiving or are planning to receive dental treatment.
7. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with simvastatin. These include:

Medicines which may increase the risk of muscle side effects, including:

- nefazodone, used to treat depression
- protease inhibitors, including indinavir, nelfinavir, ritonavir and saquinavir, used to treat HIV and other viral infections,
- erythromycin, clarithromycin and fusidic acid, used to treat infections
- ketoconazole and itraconazole, used to treat certain fungal infections
- cyclosporin, used to suppress the immune system
- danazol, used for endometriosis, menstrual disorders or hereditary angioedema
- other medicines to lower cholesterol levels, for example, gemfibrozil, fenofibrate or

nicotinic acid (also known as niacin)

- verapamil or amlodipine, used to treat high blood pressure and angina
- certain medicines used to treat heart problems, such as amiodarone or diltiazem.

If you are taking any of the above, your doctor may suggest reducing the dose or stopping this medicine temporarily or permanently.

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

- warfarin and other medicines used to prevent blood clots
- digoxin, used to treat heart problems

Grapefruit juice, especially in large amounts, may also interfere with the way this medicine works in your body. However one glass of grapefruit juice per day is unlikely to have any effect.

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with simvastatin.

How to take this medicine

Follow carefully all directions given to you by your doctor or pharmacist. Their instructions may be different to the information in this leaflet.

How much to take

Your doctor or pharmacist will tell you how much of this medicine you should take. This will depend on your cholesterol and triglyceride levels and other factors, such as kidney disease, and other medicine you may be taking.

The recommended starting dose is 10 mg or 20 mg per day, taken in the evening, which may need to be increased slowly up to 80 mg daily to

have the best effect. 80 mg is only taken if 40 mg has not reduced cholesterol levels enough.

People with Coronary Heart Disease (CHD) or at risk of getting CHD are usually started on 40 mg per day, taken in the evening.

If you are also taking certain other medicines your dose of simvastatin may be lower.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

How to take it

Swallow this medicine with a glass of water.

When to take it

Take this medicine once a day, in the evening.

The liver produces its greatest amount of cholesterol when the body is at rest and when there is no dietary intake. For most people, this is at night when asleep. Therefore, this medicine is more effective when taken in the evening. A good time would be after your evening meal. However, it does not matter whether you take it before or after food.

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

How long to take it for

Simvastatin helps to lower your cholesterol. 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 simvastatin, your cholesterol levels may rise again.

Make sure you have enough to last over weekends and holidays.

If you forget to take it

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time. Otherwise take it as soon as you remember and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for missed doses.

This may increase the chance of unwanted side effects.

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

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively go to the Accident and Emergency Department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking this medicine

Things you must do

Tell your doctor immediately if you experience any unexplained muscle pain, tenderness or weakness.

Stop taking your medicine and tell your doctor or go to a hospital immediately if you have dark or brown urine, together with the symptoms above.

Tell your doctor immediately if you have a dry cough, problems breathing, have a temperature, lose weight and/or generally feel tired.

These may be signs of a potentially fatal condition called interstitial lung disease.

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you plan to have any vaccinations or immunisations
- you become pregnant or plan to breastfeed (stop taking it and tell your doctor immediately)
- you are about to have any blood tests
- you are going to have surgery.

Have your blood cholesterol and triglycerides and liver enzymes checked when your doctor says, to make sure this medicine is working and to watch for side effects.

Have your eyes regularly checked if you are taking this medicine for a few years.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Things you must not do

Do not:

- give this medicine to anyone else, even if their symptoms seem similar to yours
- take your medicine to treat any other condition unless your doctor or pharmacist tells you to
- stop taking your medicine, or change the dosage, without first checking with your doctor.

Things to be careful of

Avoid drinking large quantities of alcohol. Drinking large amounts of alcohol may increase the chance of this medicine causing liver problems.

Very rarely, when first starting this medicine people have felt dizzy when getting up from a sitting or lying position. If this happens get up very slowly. This effect usually goes away if you keep taking this medicine.

Avoid drinking large quantities of grapefruit juice.

Grapefruit juice contains one or more components that alter the metabolism of some medicines, including simvastatin. Therefore, drinking very large quantities (over 1 litre) of grapefruit juice each day increases your chance of this medicine causing side effects. These include aching muscles, muscle tenderness or weakness, not caused by exercise. However, one glass (250 mL) of grapefruit juice each day has not been shown to have any significant effect.

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

Simvastatin generally does not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, this medicine may cause dizziness in some people. Make sure you know how you react to this medicine before you drive a car or operate machinery.

Changes to lifestyle that may help reduce the chance of coronary heart disease

Lowering high cholesterol can help reduce your chances of having coronary heart disease (CHD). However, your chances of having CHD may be increased by several other factors including high blood pressure, cigarette smoking, diabetes, excess weight, family history of CHD, being a male and being a woman who has reached menopause.

Some self-help measures suggested below may help your condition and help reduce your chances of having CHD. Talk to your doctor, pharmacist, or dietician about these measures and for more information:

- Diet - continue the low fat diet recommended by your doctor, dietician, or pharmacist.
- Weight - your doctor may advise you to lose weight if you are overweight.

- Exercise - make exercise a part of your routine - walking is good. Ask your doctor for advice before starting exercise.
- Smoking - your doctor may advise you to stop smoking or at least cut down.

Possible side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking simvastatin or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

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

This list includes the more common side effects. Mostly, these are mild:

- constipation, diarrhoea, flatulence (wind)
- stomach upset or pain, feeling or being sick (nausea or vomiting), acid regurgitation,
- headache
- dizziness
- feeling unusually tired or weak
- unable to sleep, nightmares
- hair loss
- muscle cramps
- forgetfulness
- swollen breasts
- sexual problems
- mild skin rash

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

These may be serious side effects. You may need medical attention. Most of these side effects are rare.

Muscle problems (myopathy)

Medications such as simvastatin can impair the production of certain

proteins involved in muscle metabolism and function. This can result in aching muscles, muscle tenderness or weakness

On rare occasions, muscle problems can be serious including muscle breakdown resulting in kidney damage. The risk of muscle problems is greater for patients taking higher doses of simvastatin and/or patients with kidney problems or taking certain other medicines. The risk is also greater if patients are older than 65 years and taking an 80 mg dose.

Other possible side effects which you should tell your doctor about straight away:

- signs of a potentially fatal condition called interstitial lung disease: dry cough, problems breathing, temperature, losing weight and/or generally feel tired
- tingling in the hands or feet , or numbness
- sharp pain in the upper stomach (pancreatitis)
- feeling depressed
- yellowing of the skin and/or eyes, also called jaundice
- signs of anaemia, such as tiredness, being short of breath and looking pale
- fever, flushing and/or generally feeling unwell
- severe skin rash, itchiness
- sunburn type rash after only a short time in the sun
- pinkish, itchy swellings on the skin, also called hives or nettle rash
- painful, swollen joints
- bruising more easily than normal

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

These are very serious side effects and are usually very rare. You may need urgent medical attention or hospitalisation.

- shortness of breath
- severe skin rash which may involve blistering and/or peeling of large amounts of skin
- brown or dark coloured urine, with severe muscle aching all through the body, and muscle weakness (due to muscle breakdown).

Other side effects not listed above may occur in some patients.

Allergic reactions

If you think you are having an allergic reaction to simvastatin, tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, 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
- fainting
- hay fever-like symptoms

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C. Protect from light and moisture.

Do not store your medicine, 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 this medicine 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 or pharmacist tells you to stop taking this medicine or it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Simvastatin 10 / 20 / 40 / 80 mg looks like

10 mg Tablets

Peach coloured, oval shaped, biconvex, film-coated tablets, debossed with '10' on one side and plain on other side.

20 mg Tablets

Tan coloured, oval shaped, biconvex, film-coated tablets, debossed with '20' on one side and breakline on other side.

40 mg Tablets

Brick red coloured, oval shaped, biconvex, film-coated tablets, debossed with '40' on one side and plain on other side.

80 mg Tablets

Brick red coloured, capsule shaped, biconvex, film-coated tablets, debossed with '80' on one side and '123' on other.

They are available in packs containing 30 tablets.

Not all strengths, pack types and/or pack sizes may be available.

Ingredients

Each tablet contains 10, 20, 40, or 80 mg of simvastatin as the active ingredient.

It also contains the following inactive ingredients:

- butyl hydroxyanisole
- ascorbic acid
- citric acid monohydrate

- microcrystalline cellulose
- magnesium stearate
- lactose
- pregelatinised maize starch
- OPADRY complete film coating system 20A54239 PINK (10 mg only)
- OPADRY complete film coating system 20A86525 BROWN (20 mg only)
- OPADRY complete film coating system 20A54256 PINK (40 mg only)
- OPADRY complete film coating system 20A54292 PINK (80 mg only)

This medicine is gluten-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

APO-Simvastatin 10 mg tablets

Blister pack

AUST R 149812

APO-Simvastatin 20 mg tablets

Blister pack

AUST R 149813

APO-Simvastatin 40 mg tablets

Blister pack

AUST R 149814

APO-Simvastatin 80 mg tablets

Blister pack

AUST R 149815

APO-Simvastatin 10 mg tablets

Bottle

AUST R 157731

APO-Simvastatin 20 mg tablets

Bottle

AUST R 157732

APO-Simvastatin 40 mg tablets

Bottle

AUST R 157733

APO-Simvastatin 80 mg tablets

Bottle

AUST R 157734

Sponsor

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Australia

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