

APO-Simvastatin Tablets

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.

You can also download the most up to date leaflet from www.apotex.com.au.

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 tablets. It contains the active ingredient simvastatin.

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

Simvastatin is used in 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.

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.

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 CHD (such as heart attack and angina) and stroke.

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.

How it works

Simvastatin belongs to a group of medicines known as HMG-CoA reductase inhibitors.

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

In people with high cholesterol, it works by reducing the amount of cholesterol made by the liver. In terms of good (HDL) and bad (LDL) 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

Safety and effectiveness have not been studied in boys under 10 years of age or in 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 have or have had any of the following:**
 - liver disease or unexplained high levels of liver enzymes called serum transaminases.
 - muscle pain, tenderness or weakness (myopathy) from other medicines used to treat high cholesterol or triglycerides.
- **You are taking the following medicines:**
 - gemfibrozil, used to treat high cholesterol levels
 - cyclosporin, used to suppress the immune system
 - danazol
 - fusidic acid, an antibiotic used to treat infections
 - CYP3A4 inhibitors, such as: itraconazole, ketoconazole, posaconazole and voriconazole, used to treat certain fungal

infections

- HIV protease inhibitors, e.g. indinavir, nelfinavir, ritonavir and saquinavir
- boceprevir and telaprevir, hepatitis C virus protease inhibitors
- erythromycin, clarithromycin and telithromycin, antibiotics used to treat infections
- nefazodone, used to treat depression.

- **You are pregnant**

Or there is a chance that you could become pregnant (e.g. 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 are hypersensitive to, or 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: cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

- You are allergic or intolerant to lactose. These tablets contain lactose.
- 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.

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
 - unexplained muscle pain, tenderness or weakness not caused by exercise.
3. You drink alcohol regularly.
4. You are taking niacin (also known as nicotinic acid) or a niacin-containing product, particularly if you are Chinese.
5. You are currently pregnant or you plan to become pregnant. Simvastatin must not be used during pregnancy or if there is a possibility of pregnancy.
6. You are currently breastfeeding or you plan to or breastfeed. Simvastatin must not be used or while breastfeeding.

7. You are planning to have surgery or an anaesthetic.
8. You are currently receiving or are planning to receive dental treatment.
9. 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 must not be taken with simvastatin, these include:

- nefazodone, used to treat depression
- gemfibrozil, used to treat high cholesterol levels
- cyclosporin, used to suppress the immune system
- danazol
- fusidic acid, an antibiotic used to treat infections
- medicines known as 'CYP3A4 inhibitors', such as: itraconazole, ketoconazole, posaconazole and voriconazole, used to treat certain fungal infections
- medicines containing cobicistat (a drug used in the treatment of HIV infection)
- HIV protease inhibitors, e.g. indinavir, nelfinavir, ritonavir and saquinavir
- boceprevir and telaprevir, hepatitis C virus protease inhibitors
- erythromycin, clarithromycin and telithromycin, antibiotics used to treat infections

Some other medicines may interact with simvastatin. These include:

- other medicines used to lower cholesterol levels, such as other fibrates, niacin (also known as nicotinic acid)
- warfarin and other medicines used to prevent blood clots
- colchicine, used for gout
- verapamil, diltiazem or amlodipine, used to treat high blood pressure, angina or other heart conditions
- amiodarone, used to treat irregular heart beat
- digoxin, used to treat heart problems
- lomitapide, a medicine used to treat a serious and rare genetic cholesterol condition

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.

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

How to take this medicine

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

How much to take

Your doctor 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 medicines you may be taking.

For high cholesterol and triglyceride levels, the recommended starting dose is 10 mg or 20 mg per day, taken in the evening.

For CHD or risk of CHD, the usual starting dose is 40 mg per day, taken in the evening.

The maximum dose of simvastatin is 80 mg per day taken in the evening. This dose should only be used in patients at a high risk of heart problems who have not achieved their treatment goals on lower doses.

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 you experiencing 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 that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breast-feed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side

effects. Go to your doctor regularly for a check-up.

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 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.

Avoid drinking large quantities of grapefruit juice.

Grapefruit juice contains one or more components that alter the metabolism of some medicines, including simvastatin.

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.

Possible side effects

Tell your doctor 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 if you notice any of the following:

- constipation, diarrhoea, flatulence (wind)
- stomach upset or pain, feeling or being sick (nausea or vomiting), acid regurgitation,
- headache
- dizziness
- hair loss
- muscle cramps
- trouble sleeping
- poor memory, memory loss, confusion
- erectile dysfunction.

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:

- feelings of depression
- 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
- signs of anaemia, such as tiredness, being short of breath and looking pale
- fever, flushing and/or generally feeling unwell
- 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
- larger breasts than normal in men
- brown or dark coloured urine, with severe muscle aching all through the body, and muscle weakness (due to muscle breakdown).

On rare occasions, muscle problems can be serious, including muscle breakdown resulting in kidney damage that can lead to death. The risk of muscle problems is greater for:

- patients taking higher doses of simvastatin, particularly the 80 mg dose
- older patients (65 years of age and older)
- female patients
- patients with abnormal kidney function
- patients with thyroid problems.

Liver problems can also occur and may be serious. Your doctor will do blood tests to check your liver.

Tell your doctor immediately if you have the following symptoms of liver problems:

- feeling unusually tired or weak
- loss of appetite
- sharp pain in the upper stomach (pancreatitis)
- yellowing of the skin and/or eyes, also called jaundice
- dark urine.

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 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 tablet looks like

New Formulation

10 mg Tablets

Light pink coloured, oval, biconvex film-coated tablets, marked 'SVN 10' on one side and 'NEO' on the other side.

20 mg Tablets

Tan coloured, oval, biconvex film-coated tablets, marked 'SVN 20' on one side and 'NEO' on the other side.

40 mg Tablets

Pink coloured, oval, biconvex film-coated tablets, marked 'SVN 40' on one side and 'NEO' on the other side.

80 mg Tablets

Pink coloured, capsule-shaped, biconvex film-coated tablets marked with 'SVN 80' on one side and 'NEO' on the other side.

Blister packs and bottles of 30 tablets.

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

Old Formulation

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 blister packs and bottles containing 30 tablets.

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

Ingredients

New Formulation

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

It also contains the following inactive ingredients:

- butylated hydroxyanisole
- ascorbic acid
- citric acid monohydrate
- microcrystalline cellulose
- magnesium stearate
- lactose
- pregelatinised maize starch
- Opadry 20A54692 Pink (10 mg only)
- Opadry 20A56767 Brown (20 mg only)
- Opadry 20A54535 Pink (40 mg and 80mg only)

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

Old Formulation

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

It also contains the following inactive ingredients:

- butylated 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

New Formulation

APO-Simvastatin 10 mg tablet (blister pack): AUST R 223448.

APO-Simvastatin 20 mg tablet (blister pack): AUST R 223449.

APO-Simvastatin 40 mg tablet (blister pack): AUST R 223450.

APO-Simvastatin 80 mg tablet (blister pack): AUST R 223451.

APO-Simvastatin 10 mg tablet (bottle): AUST R 223452.

APO-Simvastatin 20 mg tablet (bottle): AUST R 223453.

APO-Simvastatin 40 mg tablet (bottle): AUST R 223454.

APO-Simvastatin 80 mg tablet (bottle): AUST R 223455.

Old Formulation

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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