

SIMVASTATIN-SPIRIT TABLETS

contain the active ingredient simvastatin

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about SIMVASTATIN-SPIRIT. 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 SIMVASTATIN-SPIRIT 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 the medicine.
You may need to read it again.

What SIMVASTATIN-SPIRIT is used for

SIMVASTATIN-SPIRIT helps to lower cholesterol and triglyceride levels.

SIMVASTATIN-SPIRIT 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-SPIRIT may be used in these people, regardless of their 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-SPIRIT 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 your

blood 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 SIMVASTATIN-SPIRIT works

SIMVASTATIN-SPIRIT 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-SPIRIT reduces the bad cholesterol and raises the good cholesterol.

SIMVASTATIN-SPIRIT does **not** reduce the cholesterol and triglycerides that come from fat in food. **Therefore, when you are taking SIMVASTATIN-SPIRIT, 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.

SIMVASTATIN-SPIRIT is not recommended for use in children, as there have been no studies of its effects in children.

Your doctor may have prescribed SIMVASTATIN-SPIRIT for another reason. Ask your doctor if you have any questions about why

SIMVASTATIN-SPIRIT has been prescribed for you.

SIMVASTATIN-SPIRIT is not addictive.

Before you take SIMVASTATIN-SPIRIT

When you must not take it

Do not take SIMVASTATIN-SPIRIT if:

- **you have an allergy to SIMVASTATIN-SPIRIT, other brands of simvastatin, or any of the ingredients listed at the end of this leaflet**

Symptoms of an allergic reaction may include skin rash, itchiness, shortness of breath, swelling of the tongue or face, or painful joints.

- **you are pregnant or breast-feeding**

Your baby may absorb this medicine in the womb or from breast milk and therefore there is a possibility of harm to the baby.

- **you have liver disease**

- **you have had muscle pain, tenderness or weakness from other medicines used to treat high cholesterol or triglycerides**

- **the packaging is torn or shows signs of tampering**

- **the expiry date on the pack has passed.**

If you take this medicine after the expiry date has passed, it may not work.

If you are not sure whether you should start taking SIMVASTATIN-SPIRIT, talk to your doctor.

Before you start to take it

Tell your doctor if:

1. **you intend to become pregnant or plan to breast-feed.**

SIMVASTATIN-SPIRIT should not be used during pregnancy or while breastfeeding.

2. **you have unexplained muscle pain, tenderness or weakness not caused by exercise. This is because on rare occasions, muscle problems can be serious, including muscle breakdown resulting in kidney damage that can lead to death.**

Your doctor may do a blood test to check for certain muscle problems.

3. **you are taking niacin or a niacin-containing product, particularly if you are Chinese.**

4. **you have ever had liver disease.**
Your doctor will do a blood test to make sure you have no problems with your liver.

5. **you have kidney disease or any other medical problems.**

6. **you drink alcohol regularly.**

7. **you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.**

If you have not told your doctor about any of the above, tell them before you take any SIMVASTATIN-SPIRIT.

Taking other medicines

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

Some medicines should not be taken with SIMVASTATIN-SPIRIT as they may increase the risk of muscle side effects with SIMVASTATIN-SPIRIT. It is particularly important to tell your doctor if you are taking:

- nefazodone, used to treat depression
- protease inhibitors, used to treat HIV infection, including indinavir, nelfinavir, ritonavir, saquinavir
- certain hepatitis C virus protease inhibitors (such as boceprevir or telaprevir)
- gemfibrozil, used to treat high cholesterol levels
- cyclosporin, used to suppress the immune system

- danazol
- erythromycin, clarithromycin, telithromycin and fusidic acid antibiotics used to treat infections
- ketoconazole, itraconazole, posaconazole and voriconazole used to treat certain fungal infections

If you are taking any of the above, your doctor may suggest stopping SIMVASTATIN-SPIRIT temporarily or permanently.

Some medicines and SIMVASTATIN-SPIRIT may interfere with each other. Because taking SIMVASTATIN-SPIRIT with any of the following medicines can increase the risk of muscle problems (see Side effects), it is particularly important to tell your doctor if you are taking:

- other medicines to lower cholesterol levels, for example, other fibrates, nicotinic acid (also known as niacin)
 - verapamil, diltiazem or amlodipine used to treat high blood pressure, angina or other heart conditions
 - warfarin, or other drugs used to prevent blood clots
 - colchicine, used for gout
 - amiodarone, used to treat irregular heart beat
 - digoxin, used to treat heart failure
- Tell your doctor if you are taking nicotinic acid (also known as niacin) or a nicotinic acid containing product and you are Chinese.

These medicines may be affected by SIMVASTATIN-SPIRIT, may affect how well it works, or may increase the risk of side effects with SIMVASTATIN-SPIRIT. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking SIMVASTATIN-SPIRIT.

You should also tell any doctor who is prescribing a new medication for

you that you are taking SIMVASTATIN-SPIRIT.

How to take SIMVASTATIN-SPIRIT

How much to take

Take SIMVASTATIN-SPIRIT only when prescribed by your doctor.

Your doctor will tell you how many tablets you need to take each day. This depends on your cholesterol and triglyceride levels and other factors, such as kidney disease.

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

Because of the increased risk of muscle problems, the 80 mg dose is only for patients at high risk of heart disease problems who have not reached their cholesterol goal on lower doses.

People with CHD or risk factors for CHD are usually started on 40 mg per day, taken in the evening.

Swallow SIMVASTATIN-SPIRIT with a glass of water.

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

They may differ from the information contained in this leaflet.

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

When to take it

Take SIMVASTATIN-SPIRIT 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, SIMVASTATIN-SPIRIT 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 SIMVASTATIN-SPIRIT at about the same time each evening.

How long to take it

SIMVASTATIN-SPIRIT helps 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-SPIRIT, your cholesterol levels may rise again.

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 have trouble remembering to take your tablets, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 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 SIMVASTATIN-SPIRIT. Do this even if there are no signs of discomfort or poisoning.

While you are using SIMVASTATIN-SPIRIT

Things you must do

If you become pregnant while you are taking SIMVASTATIN-

SPIRIT, stop taking it and contact your doctor immediately.

Have your blood fats checked when your doctor says, to make sure SIMVASTATIN-SPIRIT is working.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking SIMVASTATIN-SPIRIT.

If you are about to have elective surgery, tell your doctor that you are taking SIMVASTATIN-SPIRIT.

Your doctor may suggest stopping the tablets a few days before surgery.

Things you must not do

Do not give SIMVASTATIN-SPIRIT to anyone else, even if they have the same condition as you.

Things to be careful of

Avoid drinking large quantities of alcohol.

Drinking large quantities of alcohol may increase your chance of SIMVASTATIN-SPIRIT causing liver problems.

Grapefruit juice should be avoided while taking SIMVASTATIN-SPIRIT.

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

Be careful driving or operating machinery until you know how SIMVASTATIN-SPIRIT affects you.

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

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking SIMVASTATIN-SPIRIT.

SIMVASTATIN-SPIRIT helps most people with high cholesterol, but it may have unwanted side effects in a few people. 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:

- constipation, diarrhoea, wind
- stomach upset or pain, feeling sick (nausea)
- headache
- dizziness

These are the more common side effects of SIMVASTATIN-SPIRIT. For the most part, these have been mild and short-lived.

Tell your doctor immediately if you notice any of the following:

- aching muscles, muscle tenderness or weakness, not caused by exercise (in very rare cases this may not go away after stopping SIMVASTATIN-SPIRIT)
- brown/black coloured urine

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

Tell your doctor immediately if you notice any of the following:

- tingling in the hands or feet
- signs of anaemia, such as tiredness, being short of breath, and looking pale
- fever, generally feeling unwell
- skin rash, itchiness
- pinkish, itchy swellings on the skin, also called hives or nettlerash
- painful, swollen joints
- bruising more easily than normal
- larger breasts than normal in men

These may be serious side effects of SIMVASTATIN-SPIRIT. Some of these may be symptoms of an allergic reaction to SIMVASTATIN-SPIRIT. You may need urgent medical attention. Serious side effects are rare.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- swelling of the face, lips, mouth, throat or tongue which may cause difficulty in swallowing or breathing
- shortness of breath

These are serious side effects. If you have them, you may have had a **serious allergic reaction to SIMVASTATIN-SPIRIT**. You may need urgent medical attention or hospitalisation. Serious side effects are rare.

Also, tell your doctor if you notice:

- hair loss
- muscle cramps
- trouble sleeping
- poor memory, memory loss, confusion
- feelings of depression
- erectile dysfunction
- breathing problems including persistent cough and/or shortness of breath or fever

These are other side effects that have been reported with simvastatin.

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:

- feel tired or weak
- loss of appetite
- upper belly pain
- dark urine
- yellowing of your skin or the whites of your eyes

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

Tell your doctor if you notice any other effects.

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

After using SIMVASTATIN-SPIRIT

Storage

Keep your tablets in the blister pack until it is time to take them.

If you take the tablets out of the blister pack, they may not keep well.

Keep SIMVASTATIN-SPIRIT in a cool dry place where the temperature stays below 25°C. Do not store it or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on window sills.

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 SIMVASTATIN-SPIRIT or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

SIMVASTATIN-SPIRIT comes in four types of tablets:

- SIMVASTATIN-SPIRIT simvastatin 10 mg - pink coloured, shield-shaped tablet with "SV 10" marked on one side
- SIMVASTATIN-SPIRIT simvastatin 20 mg - tan coloured, shield-shaped tablet with "SV 20" marked on one side
- SIMVASTATIN-SPIRIT simvastatin 40 mg - pink coloured, shield-shaped tablet with "SV 40" marked on one side.
- SIMVASTATIN-SPIRIT simvastatin 80 mg - pink coloured, capsule-shaped tablet with "SV 80" marked on one side.

SIMVASTATIN-SPIRIT comes in blister packs containing 30 tablets.

Ingredients

Active ingredient:

- SIMVASTATIN-SPIRIT 10 mg simvastatin per tablet
- SIMVASTATIN-SPIRIT 20 mg simvastatin per tablet
- SIMVASTATIN-SPIRIT 40 mg simvastatin per tablet
- SIMVASTATIN-SPIRIT 80 mg simvastatin per tablet

Inactive ingredients:

- butylated hydroxyanisole
- ascorbic acid
- citric acid monohydrate
- cellulose-microcrystalline
- starch - pregelatinised maize
- magnesium stearate
- lactose
- purified talc
- Opadry II Pink 40L14842 (10 mg only)
- Opadry II Flesh Y-22-13577 (20 mg only)
- Opadry II Pink 32K14834 (40 mg only)
- Opadry II Pink 40L14278 (80 mg only)

The tablets are gluten free.

Sponsor

SIMVASTATIN-SPIRIT is supplied in Australia by:

Spirit Pharmaceuticals Pty Ltd

117 Harrington Street,
The Rocks, Sydney NSW 2000
Australia
1800 065 772

Australian Register Numbers:

SIMVASTATIN-SPIRIT simvastatin
10 mg Blister pack AUST R 116701
SIMVASTATIN-SPIRIT simvastatin
20 mg Blister pack AUST R 116702
SIMVASTATIN-SPIRIT simvastatin
40 mg Blister pack AUST R 116704
SIMVASTATIN-SPIRIT simvastatin
80 mg Blister pack AUST R 116705

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