

Pharmaniaga Simvastatin Tablet

Simvastatin (10 mg/20 mg/40 mg)

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What Pharmaniaga Simvastatin Tablet is used for

Your doctor has prescribed Pharmaniaga Simvastatin Tablet to reduce the health risks associated with coronary heart disease (CHD).

If you have CHD, diabetes, history of stroke, or other vessel disease (regardless of the amount of cholesterol in your blood), Pharmaniaga Simvastatin Tablet:

- Can prolong your life by reducing the risk of heart disease or stroke
- Reduce the need for surgery to increase blood flows to the legs and major organs such as the heart
- Reduce the need for hospitalization for chest pain (called angina).

Pharmaniaga Simvastatin Tablet reduces the amount of cholesterol in your blood. Cholesterol can cause CHD by clogging the blood vessels that carry oxygen and nutrients to the heart. This clogging, or hardening of the arteries, is called atherosclerosis. Atherosclerosis can lead to chest pain (called angina) and heart attack. Pharmaniaga Simvastatin Tablet also slows the progression of atherosclerosis and reduces the development of new atherosclerosis.

High cholesterol results from many factors, including eating foods high in saturated fats, certain diseases or genetic conditions, and lack of exercise.

Lowering high cholesterol can help reduce your chances of having coronary heart disease (CHD).

LDL-cholesterol is called "bad" cholesterol because it is the cholesterol that clogs your arteries. HDL, on the other hand, is thought to remove cholesterol from the blood vessels and is, therefore, considered to be "good" cholesterol.

Pharmaniaga Simvastatin Tablet works by decreasing the production of cholesterol in the liver (the largest source of cholesterol within the body) and increasing the removal of cholesterol from your bloodstream by your liver. By combining Pharmaniaga Simvastatin Tablet with your diet, you take control of the amount of cholesterol you eat and the amount your body produces.

In most people, there are no immediate symptoms of high cholesterol. Your doctor can measure your cholesterol with a simple blood test. Visit your doctor regularly, keep track of your cholesterol, and discuss your goals with your doctor.

How Pharmaniaga Simvastatin Tablet works

Simvastatin is the drug classified as statins. It works by blocking HMG-CoA enzyme that involves in cholesterol production. Therefore, less cholesterol is made and reduces cholesterol levels in the blood. Simvastatin lowers the level of total cholesterol, 'bad' cholesterol (LDL, low density lipoprotein) and fatty substances called triglycerides. It raises 'good' cholesterol (HDL, high density lipoprotein).

Before you use Pharmaniaga Simvastatin Tablet

- When you must not use it

Do not take Pharmaniaga Simvastatin Tablet if:

- You have an allergic to simvastatin or any of the ingredients of this medicine (listed in Product Description)
- Diagnosed with active liver disease
- Pregnant or breast-feeding
- Taking any of the following medicines:

- certain antifungal medicines (such as itraconazole, ketoconazole, posaconazole, or voriconazole)
- HIV protease inhibitors (such as indinavir, nelfinavir, ritonavir, and saquinavir)
- Hepatitis C antiviral agents (such as boceprevir, telaprevir, elbasvir, or grazoprevir)
- certain antibiotics (such as erythromycin, clarithromycin, or telithromycin)
- antidepressant nefazodone
- medicines containing cobicistat (used as an enhancer for antiretroviral agents)
- gemfibrozil (a fibric acid medicine for lowering cholesterol)
- cyclosporine (used as an immunosuppressant medicine to prevent organ transplant rejection)
- danazol (used in treatment of endometriosis, fibrocystic breast disease and angioedema)

Ask your doctor if you are not sure if your medicine is listed above.

- Before you start to use it

Tell your doctor or pharmacist before taking Pharmaniaga Simvastatin Tablet if:

- you have or have had myasthenia (a disease with general muscle weakness including in some cases muscles used when breathing), or ocular myasthenia (a disease causing eye muscle weakness) as statins may sometimes aggravate the condition.
- 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.
- You have ever had liver disease. Your doctor will do a blood test to

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make sure you have no problems with your liver.

- You have kidney disease or any other medical problems.
- You drink alcohol regularly.
- You have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.

Use in pregnancy and breastfeeding

Pharmaniaga Simvastatin Tablet should not be used in women who are pregnant, trying to become pregnant or suspect that they are pregnant. If you become pregnant while taking Pharmaniaga Simvastatin Tablet, stop taking it and contact your doctor immediately.

Women taking Pharmaniaga Simvastatin Tablet should not breastfeed.

If you have not told your doctor about any of the above, tell them before you take any Pharmaniaga Simvastatin Tablet.

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicine. This includes medicines obtained without a prescription from your pharmacy, supermarket or health food shop, including herbal medicines.

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

- antifungal agents (such as itraconazole, ketonazole, posaconazole or voriconazole)
- boceprevir or telaprevir (drugs used to treat hepatitis C virus infection)
- antidepressant nefazodone
- medicine containing cobistat
- cyclosporine

- protease inhibitors, used to treat HIV infection, including indinavir, nelfinavir, ritonavir, saquinavir.
- fibric acid derivatives (such as gemfibrozil and bezafibrate)
- danazol
- antibiotics erythromycin, clarithromycin, telithromycin and fusidic acid
- amiodarone (a drug used to treat an irregular heartbeat)
- verapamil, diltiazem, or amlodipine (drugs used to treat high blood pressure, angina, or other heart conditions)
- lomitapide (a drug used to treat a serious and rare genetic cholesterol condition)
- daptomycin (a drug used to treat complicated skin and skin structure infections and bacteremia)
- grapefruit juice (which should be avoided while taking Pharmaniaga Simvastatin Tablet)

It is also important to tell your doctor if you are taking anticoagulants (drugs that prevent blood clots, such as warfarin, phenprocoumon or acenocoumarol), colchicine (a medicine used for gout), niacin, or fenofibrate, another fibric acid derivative.

If you are taking any of the above, your doctor may suggest stopping Pharmaniaga Simvastatin Tablet temporarily or permanently.

Some medicines and Pharmaniaga Simvastatin Tablet may interfere with each other.

How to use Pharmaniaga Simvastatin Tablet

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 on the label, ask your doctor or pharmacist for help.

- How much to use

For adults, the recommended dosage range is 5-80mg per day, taken in the evening, which may need to be

increased up to 80 mg daily to have the best effect.

For patients at High Risk of Coronary Heart Disease (CHD) or with existing CHD: The recommended dosage of Pharmaniaga Simvastatin Tablet starts at 40 mg daily in the evening.

For patients with Hyperlipidemia (who are not in the risk categories above): You should be placed on a standard cholesterol-lowering diet before receiving Pharmaniaga Simvastatin Tablet and should continue on this diet during treatment with Pharmaniaga Simvastatin Tablet. The recommended starting dose is 20mg per day given as a single dose a day in the evening. Anyone who require a large a reduction in LDL-C (more than 45%) may be started at 40mg per day given as single dose in the evening.

For individuals with Homozygous Familial Hypercholesterolemia: The recommended dosage is 40mg daily in the evening. The 80mg dose is recommended when benefits are expected to outweigh the potential risks.

For kidney insufficiency: The recommended dosage above 10mg/day should be carefully considered and if deemed necessary, implemented cautiously.

Uses in children (10 – 17 years old), the recommended usual starting dose is 10 mg a day in the evening. The maximum recommended dose is 40 mg a day. Pharmaniaga Simvastatin Tablet is not recommended for paediatric use. Safety and effectiveness in paediatric patients have not been established.

Your doctor may prescribe lower doses, particularly if you are taking certain medications listed above or have certain kidney conditions. Keep taking Pharmaniaga Simvastatin Tablet unless your doctor tells you to stop. If you stop taking Pharmaniaga Simvastatin Tablet, your cholesterol may rise again.

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- When to use it

Take Pharmaniaga Simvastatin Tablet once a day in the evening. Taking your tablet at the same time each evening will have the best effect.

- How long to use it

Pharmaniaga Simvastatin Tablet 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 Pharmaniaga Simvastatin Tablet, your cholesterol levels may rise again.

- If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you or anyone else may have use too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using Pharmaniaga Simvastatin Tablet

- Things you must do

If you become pregnant while you are taking Pharmaniaga Simvastatin Tablet, stop taking it and contact your doctor immediately.

Have your blood fats checked when your doctor says, to make sure Pharmaniaga Simvastatin Tablet is working.

If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking Pharmaniaga Simvastatin Tablet.

If you are about to have elective surgery, tell your doctor that you are

taking Pharmaniaga Simvastatin Tablet. Your doctor may suggest stopping the tablets a few days before surgery.

- Things you must not do

Do not give Pharmaniaga Simvastatin Tablet 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 Pharmaniaga Simvastatin Tablet causing liver problems.

Grapefruit juice should be avoided while taking Pharmaniaga Simvastatin Tablet. Grapefruit juice contains one or more components that alter the metabolism of some medicines, including Pharmaniaga Simvastatin Tablet.

Be careful driving or operating machinery until you know how Pharmaniaga Simvastatin Tablet affects you. Pharmaniaga Simvastatin Tablet generally does not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, Pharmaniaga Simvastatin Tablet may cause dizziness in some people. Make sure you know how you react to Pharmaniaga Simvastatin Tablet before you drive a car or operate machinery.

Side effects

Pharmaniaga Simvastatin Tablet 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.

Possible side effects are:

- Gastrointestinal disturbance
- Headache/dizziness

- Increased in serum aminotransferase.
- Muscle pain and weakness.
- Myasthenia gravis (a disease-causing general muscle weakness including in some cases muscles used when breathing).
- Ocular myasthenia (a disease-causing eye muscle weakness)

Talk to your doctor if you experience weakness in your arms or legs that worsens after period of activity, double vision or drooping of your eyelids, difficulty swallowing, or shortness of breath. If you have muscle problems that do not go away even after your doctor has told you to stop taking Pharmaniaga Simvastatin Tablet, please refer to your doctor. Your doctor may do further tests to diagnose the cause of your muscle problems.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist immediately or go to accident and emergency at your nearest hospital.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Pharmaniaga Simvastatin Tablet

- Storage

Keep all medicines out of the sight and reach of children

Do not use Pharmaniaga Simvastatin Tablet after the expiry date stamped on the pack.

Store below 30°. Protect from light.

Disposal

Medicines should not be disposed of via wastewater or house hold waste. Ask your pharmacist how to dispose of medicines

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no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Pharmaniaga Simvastatin Tablet 10 mg

Peach, oval shaped, biconvex, film-coated tablets with 'SIM 10' marking on one side and scored on the other.

Pharmaniaga Simvastatin Tablet 20 mg

Brown, oval-shaped, biconvex, film-coated tablet, plain on one side and scored on the other.

Pharmaniaga Simvastatin Tablet 40 mg

Red, oblong, film-coated tablet, embossed 'Pharmaniaga icon' on one side and scored on the other.

- Ingredients

Pharmaniaga Simvastatin Tablet 10mg contain

Active ingredient

Simvastatin

Inactive ingredients

Butylated Hydroxy Toluene, Citric Acid Anhydrous, Ethanol, Starch, Lactose Monohydrate, Microcrystalline Cellulose, Magnesium Stearate, Ascorbic Acid Opadry Pink.

Pharmaniaga Simvastatin Tablet 20mg contain

Active ingredients

Simvastatin 20mg

Inactive ingredients

Starch, Citric Acid Anhydrous, Lactose Monohydrate, Butylated Hydroxyl Toluene, Ascorbic Acid, Microcrystalline Cellulose, Opadry II Brown, Ethanol, Magnesium Stearate.

Pharmaniaga Simvastatin Tablet 40mg contain

Active ingredients

Simvastatin 40mg

Inactive ingredients

Lactose Monohydrate, Ascorbic acid, Opadry II Pink, Citric Acid Anhydrous, Microcrystalline Cellulose, Ethanol, Starch, Magnesium Stearate, Butylated Hydroxyl Toluene

- MAL number(s):

Pharmaniaga Simvastatin Tablet 10 mg

MAL20020475AZ

Pharmaniaga Simvastatin Tablet 20 mg

MAL20020476AZ

Pharmaniaga Simvastatin Tablet 40 mg

MAL20020477AZ

Manufacturer & Product Registration Holder

Pharmaniaga Manufacturing Berhad
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