

ZOCOR[®]

Simvastatin (10mg, 20mg, 40mg)

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What *ZOCOR* is used for

Your doctor has prescribed *ZOCOR* 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), *ZOCOR*:

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

ZOCOR 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. *ZOCOR* 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). CHD can have many causes. Your chances of having CHD may be increased by several factors, which include:

- high cholesterol,
- high blood pressure,
- cigarette smoking,
- diabetes,
- excess weight,
- family history of CHD,
- male gender, and
- post-menopause.

You can help control the first five of these causes of CHD.

WHAT YOU CAN DO TO HELP STAY HEALTHY AND REDUCE YOUR CHANCES OF CORONARY HEART DISEASE.

STOP SMOKING

Smoking increases your chances of a heart attack.

EXERCISE

May raise your levels of "good" cholesterol and reduce your chances of having CHD. Ask your doctor for advice before starting exercise.

SEE YOUR DOCTOR REGULARLY

Your doctor will check your cholesterol.

TAKE YOUR MEDICATION

Keep up with your therapy to keep your cholesterol under control.

MAINTAIN THE DIET RECOMMENDED BY YOUR DOCTOR

Your diet will not only help you reduce your cholesterol but will also help you lose weight (if appropriate).

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.

ZOCOR 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 *ZOCOR* 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 *ZOCOR* works

ZOCOR reduces the level of LDL (bad) cholesterol and fatty substances called triglycerides in your blood and raises HDL (good) cholesterol. It is a member of the class of drugs called hydroxymethylglutaryl-coenzyme A (HMG-CoA) reductase inhibitors.

Before you take *ZOCOR*

- When you must not take it

Do not take *ZOCOR* if you are:

- allergic to any of its components
- 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)

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- 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
- gemfibrozil (a fibric acid medicine for lowering cholesterol)
- cyclosporine
- danazol.

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

- Before you start to take it

Tell your doctor about any medical problems you have or have had, and about any allergies.

Tell your doctor if you have or have had myasthenia (a disease with general muscle weakness including in some cases muscles used for breathing) or ocular myasthenia (a disease causing eye muscle weakness) as statins may sometimes aggravate the condition or lead to the occurrence of myasthenia.

Tell your doctor if you consume substantial quantities of alcohol or have a past history of liver disease.

Tell your doctor if you are Asian.

Use in children

Safety and effectiveness have been studied in 10-17 year old boys and in girls, who had started their menstrual period at least one year before (see “**How to take ZOCOR**”). ZOCOR has not been studied in children under the age of 10 years. For more information, talk to your doctor.

Use in pregnancy and breast-

feeding

ZOCOR 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 ZOCOR, stop taking it and contact your doctor immediately.

Women taking ZOCOR should not breast-feed.

- Taking other medicines

You should tell your doctor about all drugs that you are using or plan to use, including those obtained without a prescription, while taking ZOCOR. You should also tell any doctor who is prescribing a new medication for you that you are taking ZOCOR.

Because taking ZOCOR with any of the following drugs or substances can increase the risk of muscle problems (see “**Side Effects**”), it is particularly important to tell your doctor if you are taking:

- antifungal agents (such as itraconazole, ketoconazole, posaconazole, or voriconazole)
- HIV protease inhibitors (such as indinavir, nelfinavir, ritonavir, and saquinavir)
- boceprevir or telaprevir (drugs used to treat hepatitis C virus infection)
- the antibiotics erythromycin, clarithromycin, telithromycin, and fusidic acid
- the antidepressant nefazodone
- medicines containing cobicistat
- cyclosporine
- danazol
- fibric acid derivatives (such as gemfibrozil and bezafibrate)
- 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)
- ticagrelor (a drug used to prevent blood clots)
- grapefruit juice (which should be avoided while taking ZOCOR)

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, orfenofibrate, another fibric acid derivative.

Some of these have already been listed in the above section “**Before you take ZOCOR, When you must not take it**”.

How to take ZOCOR

- How much to take

Your doctor has prescribed your dose of ZOCOR. Take ZOCOR exactly as your doctor tells you to take it. For adults, the usual starting dose is 20 or 40 mg a day, given as a single dose in the evening. Your doctor may adjust your dose to a maximum of 80 mg a day, given as a single dose in the evening.

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.

For 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.

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

- When to take it

ZOCOR is recommended to be taken in the evening.

- How long to take it

Continue to take ZOCOR for as long as your doctor recommends.

- If you forget to take it

If you miss a dose, do not take an extra dose. Just resume your usual schedule.

- If you use too much (overdose)

Contact your doctor immediately.

While you are using ZOCOR

- Things you must do

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

Have your blood fats checked when your doctor says, to make sure ZOCOR is working.

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

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

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

- Things you must not do

Do not give ZOCOR 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 ZOCOR causing liver problems.

Grapefruit juice should be avoided while taking ZOCOR.

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

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

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

Side Effect

Any medicine may have unintended or undesirable effects, so-called side effects. ZOCOR is generally well tolerated. For the most part side effects have been mild and short-lived. The most common side effects are digestive disturbances. Less common are weakness and headache. Still less common are muscle pain, tenderness or weakness (that in very rare cases may not go away after stopping ZOCOR), liver problems (sometimes serious), poor memory, memory loss, confusion, trouble sleeping, depression, erectile dysfunction, breathing problems including persistent cough and/or shortness of breath or fever, and hypersensitivity (allergic reactions which may have a number of symptoms, including joint pain, fever, shortness of breath, rash, swelling of the face,

lips, tongue, and/or throat that may cause difficulty in swallowing).

Increases in fasting blood sugar have also been reported with this group of medicines.

Contact your doctor promptly if you experience muscle pain, tenderness, or weakness. This is because on rare occasions, muscle problems can be serious, including muscle breakdown resulting in kidney damage that can lead to death.

This risk of muscle breakdown is greater for patients taking higher doses of ZOCOR, particularly the 80-mg dose. This risk of muscle breakdown is also greater for older patients (65 years of age and older), female patients, patients with abnormal kidney function, and patients with thyroid problems.

If you have muscle problems that do not go away even after your doctor has told you to stop taking ZOCOR, please refer to your doctor. Your doctor may do further tests to diagnose the cause of your muscle problems.

Unknown frequency:

- 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 periods of activity, double vision or drooping of your eyelids, difficulty swallowing, or shortness of breath.

See your doctor regularly to check your cholesterol level and

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to check for side effects. Your doctor should do blood tests to check your liver before you start

- 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 may also occur rarely, and as with any prescription drug, some side effects may be serious. Ask your doctor or pharmacist for more information.

Tell your doctor or pharmacist if you develop any unusual symptom or if any known symptom persists or worsens.

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

Storage and Disposal of ZOCOR

- Storage

For ZOCOR 10mg, 20mg and 40mg, store below 30°C. Keep all medicines safely away from children.

How long will my medicine last? Do not use this medicine after the date shown by the four numbers following EX (or EXP) on the container. The

taking ZOCOR and if you have any symptoms of liver problems while you take ZOCOR. Call first two numbers indicate the month; the last two numbers indicate the year.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

ZOCOR 10mg: Peach, oval-shaped film coated tablet. One side coded MSD735, the other side plain.

ZOCOR 20mg: Tan, oval-shaped film coated tablet. One side coded MSD740, the other side plain.

ZOCOR 40mg: Brick Red, oval-shaped film coated tablet. One side coded MSD749, the other side plain.

- Ingredients

ZOCOR (simvastatin) is a tablet containing 10, 20 or 40 simvastatin as the active ingredient.

In addition, ZOCOR contains the following inactive ingredients: butylated hydroxyanisole, ascorbic acid, citric acid monohydrate, microcrystalline cellulose, pregelatinized starch, magnesium stearate, lactose monohydrate,

your doctor right away if you have the following symptoms of liver problems:

hypromellose, hydroxypropyl cellulose, titanium dioxide, talc, yellow ferric oxide (10 and 20 mg), red ferric oxide (20 and 40 mg)

- MAL number:

MAL19921415ARZ (ZOCOR TABLETS 10MG)

MAL19921416ARZ (ZOCOR TABLETS 20MG)

MAL19985911ARZ (ZOCOR 40MG TABLET)

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Product Registration Holder

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