

VYTORIN® (ezetimibe/simvastatin) Tablets

Patient Information about VYTORIN (VI-tor-in)

Generic name: ezetimibe/simvastatin tablets

Read this information carefully before you start taking VYTORIN. Review this information each time you refill your prescription for VYTORIN as there may be new information. This information does not take the place of talking with your doctor about your medical condition or your treatment. If you have any questions about VYTORIN, ask your doctor. Only your doctor can determine if VYTORIN is right for you.

What is VYTORIN?

VYTORIN contains two cholesterol-lowering medications, ezetimibe and simvastatin. VYTORIN is a prescription medicine used to lower levels of total cholesterol, LDL (bad) cholesterol, and fatty substances called triglycerides in the blood. In addition, VYTORIN raises levels of HDL (good) cholesterol. VYTORIN is for patients who cannot control their cholesterol levels by diet and exercise alone. You should stay on a cholesterol-lowering diet while taking this medicine.

VYTORIN works to reduce your cholesterol in two ways. It reduces the cholesterol absorbed in your digestive tract, as well as the cholesterol your body makes by itself. VYTORIN does not help you lose weight.

VYTORIN has not been shown to reduce heart attacks or strokes more than simvastatin alone.

The usual dose of VYTORIN is 10/10 mg to 10/40 mg 1 time each day.

VYTORIN 10/80 mg increases your chance of developing muscle damage. The 10/80 mg dose should only be used by people who:

- have been taking VYTORIN 10/80 mg chronically (such as 12 months or more) without having muscle damage
- do not need to take certain other medicines with VYTORIN that would increase your chance of getting muscle damage.

If you are unable to reach your LDL-cholesterol goal using VYTORIN 10/40 mg, your doctor should switch you to another cholesterol-lowering medicine.

For more information about cholesterol, see the section called “What should I know about high cholesterol?”

Who should not take VYTORIN?

Do not take VYTORIN if you take:

- Certain anti-fungal medicines including:
 - itraconazole
 - ketoconazole
 - posaconazole
- HIV protease inhibitors (indinavir, nelfinavir, ritonavir, saquinavir, tipranavir, or atazanavir),
- Certain antibiotics, including:
 - erythromycin
 - clarithromycin
 - telithromycin
- nefazodone
- A fibric acid medicine for lowering cholesterol called gemfibrozil
- cyclosporine

- danazol

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

Also do not take VYTORIN:

- If you are allergic to ezetimibe or simvastatin, the active ingredients in VYTORIN, or to the inactive ingredients. For a list of inactive ingredients, see the “Inactive ingredients” section at the end of this information sheet.
- If you have active liver disease or repeated blood tests indicating possible liver problems.
- If you are pregnant, or think you may be pregnant, or planning to become pregnant or breast-feeding.
- If you are a woman of childbearing age, you should use an effective method of birth control to prevent pregnancy while using VYTORIN.

VYTORIN has not been studied in children under 10 years of age.

What should I tell my doctor before and while taking VYTORIN?

Tell your doctor right away if you have unexplained muscle pain, tenderness, or weakness while you take VYTORIN. Muscle problems, including muscle breakdown, can be serious in some people and rarely cause kidney damage that can lead to death.

The risk of muscle breakdown is greater at higher doses of VYTORIN, particularly the 10/80 mg dose.

The risk of muscle breakdown is greater in people 65 years of age and older, females, and people with kidney or thyroid problems.

Taking VYTORIN with certain substances can increase the risk of muscle problems. It is especially important to tell your doctor if you take:

- fibric acid derivatives (such as fenofibrate)
- amiodarone (a drug used to treat an irregular heartbeat)
- verapamil, diltiazem, amlodipine, or ranolazine (drugs used to treat high blood pressure, chest pain associated with heart disease, or other heart conditions)
- large quantities of grapefruit juice (more than 1 quart daily)
- colchicine (a medicine used to treat gout)
- voriconazole (an anti-fungal medicine)
- large doses of niacin or nicotinic acid

Tell your doctor if you are taking niacin or a niacin-containing product, as this may increase your risk of muscle problems, especially if you are Chinese.

It is also important to tell your doctor if you are taking coumarin anticoagulants (drugs that prevent blood clots, such as warfarin).

Tell your doctor about all the medicines you take, including any prescription and nonprescription medicines, vitamins, and herbal supplements.

If you have more than 1 doctor, tell all of your doctors that you take VYTORIN. This is especially important when they prescribe a new medicine or increase the dose of your other medicines.

Tell your doctor about all your medical conditions including allergies.

Tell your doctor if you:

- drink substantial quantities of alcohol or ever had liver problems. VYTORIN may not be right for you.
- are pregnant or plan to become pregnant. Do not use VYTORIN if you are pregnant, trying to become pregnant or suspect that you are pregnant. If you become pregnant while taking VYTORIN, stop taking it and contact your doctor immediately.
- are breast-feeding. Do not use VYTORIN if you are breast-feeding.

Tell other doctors prescribing a new medication that you are taking VYTORIN.

How should I take VYTORIN?

- Take VYTORIN exactly as your doctor tells you to take it.
- Take VYTORIN once a day, in the evening, with or without food.
- If you miss a dose, do not take an extra dose. Just resume your usual schedule.
- Continue to follow a cholesterol-lowering diet while taking VYTORIN. Ask your doctor if you need diet information.
- Keep taking VYTORIN unless your doctor tells you to stop. If you stop taking VYTORIN, your cholesterol may rise again.

What should I do in case of an overdose?

Contact your doctor immediately.

What are the possible side effects of VYTORIN?

See your doctor regularly to check your cholesterol level and to check for side effects. Your doctor should do blood tests to check your liver before you start taking VYTORIN and if you have any symptoms of liver problems while you take VYTORIN. Call your doctor right away 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

In clinical studies patients reported the following common side effects while taking VYTORIN: headache, muscle pain, and diarrhea (see What should I tell my doctor before and while taking VYTORIN?).

The following side effects have been reported in general use with VYTORIN or with ezetimibe or simvastatin tablets (tablets that contain the active ingredients of VYTORIN):

- allergic reactions including swelling of the face, lips, tongue, and/or throat that may cause difficulty in breathing or swallowing (which may require treatment right away), rash, hives; raised red rash, sometimes with target-shaped lesions; joint pain; muscle pain; alterations in some laboratory blood tests; liver problems (sometimes serious); inflammation of the pancreas; nausea; dizziness; tingling sensation; depression; gallstones; inflammation of the gallbladder; trouble sleeping; poor memory; memory loss; confusion; erectile dysfunction; breathing problems including persistent cough and/or shortness of breath or fever.

Tell your doctor if you are having these or any other medical problems while on VYTORIN. This is not a complete list of side effects. For a complete list, ask your doctor or pharmacist.

What should I know about high cholesterol?

Cholesterol is a type of fat found in your blood. Cholesterol comes from two sources. It is produced by your body and it comes from the food you eat. Your total cholesterol is made up of both LDL and HDL cholesterol.

LDL cholesterol is called “bad” cholesterol because it can build up in the wall of your arteries and form plaque. Over time, plaque build-up can cause a narrowing of the arteries. This narrowing can slow or block blood flow to your heart, brain, and other organs. High LDL cholesterol is a major cause of heart disease and one of the causes for stroke.

HDL cholesterol is called “good” cholesterol because it keeps the bad cholesterol from building up in the arteries.

Triglycerides also are fats found in your body.

General Information about VYTORIN

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use VYTORIN for a condition for which it was not prescribed. Do not give VYTORIN to other people, even if they have the same condition you have. It may harm them.

This summarizes the most important information about VYTORIN. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about VYTORIN that is written for health professionals. For additional information, visit the following web site: vytorin.com.

Inactive ingredients:

Butylated hydroxyanisole NF, citric acid monohydrate USP, croscarmellose sodium NF, hypromellose USP, lactose monohydrate NF, magnesium stearate NF, microcrystalline cellulose NF, and propyl gallate NF.

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This patient information has been approved by the U.S. Food and Drug Administration

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