

Patient Information
VYTORIN[®] (VI-tor-in)
(ezetimibe and simvastatin)
Tablets

Read this Patient Information carefully before you start taking VYTORIN[®] and each time you get a refill. 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 is a prescription medicine that contains 2 cholesterol lowering medicines, ezetimibe and simvastatin. VYTORIN is used along with diet to:

- lower the level of your “bad” cholesterol (LDL)
- increase the level of your “good” cholesterol (HDL)
- lower the level of fat in your blood (triglycerides)

VYTORIN is for patients who cannot control their cholesterol levels by diet and exercise alone.

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

It is not known if VYTORIN is safe and effective in children under 10 years of age or in girls who have not started their period (menses).

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.

Who should not take VYTORIN?

Do not take VYTORIN if you take:

- Certain anti-fungal medicines including:
 - itraconazole
 - ketoconazole
 - posaconazole

- voriconazole
- HIV protease inhibitors (indinavir, nelfinavir, ritonavir, saquinavir, tipranavir, or atazanavir)
- Certain hepatitis C virus protease inhibitors (such as boceprevir or telaprevir)
- Certain antibiotics, including:
 - erythromycin
 - clarithromycin
 - telithromycin
- nefazodone
- medicines containing cobicistat
- A fibric acid medicine for lowering cholesterol called gemfibrozil
- cyclosporine
- danazol

Ask your doctor or pharmacist for a list of these medicines if you are not sure.

Also do not take VYTORIN if you:

- are allergic to ezetimibe or simvastatin or any of the ingredients in VYTORIN. See the end of this leaflet for a complete list of ingredients in VYTORIN.
- have liver problems.
- are pregnant or plan to become pregnant. VYTORIN may harm your unborn baby. If you are a woman of childbearing age, you should use an effective method of birth control to prevent pregnancy while using VYTORIN. If you become pregnant while taking VYTORIN, stop taking VYTORIN and call your doctor.
- are breastfeeding or plan to breastfeed. It is not known if VYTORIN passes into your breast milk. You and your doctor should decide the best way to feed your baby if you take VYTORIN.

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

Tell your doctor if you:

- have unexplained muscle aches or weakness
- have kidney problems
- have or have had liver problems or drink more than 2 glasses of alcohol daily
- have thyroid problems
- are 65 years of age or older
- are Chinese

Also see "What are the possible side effects of VYTORIN?"

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Tell your doctor who prescribes VYTORIN if another doctor increases the dose of another medicine you are taking.

Talk to your doctor before you start taking any new medicines.

Taking VYTORIN with certain other medicines may affect each other causing side effects. VYTORIN may affect the way other medicines work, and other medicines may affect how VYTORIN works.

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 or dronedarone (drugs 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)
- grapefruit juice (which should be avoided while taking VYTORIN)
- colchicine (a medicine used to treat gout)
- lomitapide (a medicine used to treat a serious and rare genetic cholesterol condition)
- daptomycin (a drug used to treat complicated skin and bloodstream infections)
- 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.

How should I take VYTORIN?

- Take VYTORIN exactly as your doctor tells you to take it.
- Do not change your dose or stop taking VYTORIN without talking to your doctor.
- Take VYTORIN 1 time each day in the evening.
- Take VYTORIN with or without food.
- While taking VYTORIN, continue to follow your cholesterol-lowering diet and to exercise as your doctor told you to.
- If you miss a dose, do not take an extra dose. Just resume your usual schedule.
- Your doctor should do fasting blood tests to check your cholesterol while you take VYTORIN. Your doctor may change your dose of VYTORIN if needed.

- If you take too much VYTORIN, call your doctor or Poison Control Center at 1-800-222-1222 or go to the nearest hospital emergency room right away.

What are the possible side effects of VYTORIN?

VYTORIN may cause serious side effects, including:

- **Muscle pain, tenderness and weakness (myopathy).** Muscle problems, including muscle breakdown, can be serious in some people and rarely cause kidney damage that can lead to death.

Tell your doctor right away if:

- **you have unexplained muscle pain, tenderness, or weakness, especially if you have a fever or feel more tired than usual, while you take VYTORIN.**
- you have muscle problems that do not go away even after your doctor has advised you to stop taking VYTORIN. Your doctor may do further tests to diagnose the cause of your muscle problems.

Your chances of getting muscle problems are higher if you:

- are taking certain other medicines while you take VYTORIN
 - are 65 years of age or older
 - are female
 - have thyroid problems (hypothyroidism) that are not controlled
 - have kidney problems
 - are taking higher doses of VYTORIN, particularly the 10/80 mg dose
 - are Chinese
- **Liver problems.** 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:
 - loss of appetite
 - upper belly pain
 - dark urine
 - yellowing of your skin or the whites of your eyes
 - feel tired or weak

The most common side effects of VYTORIN include:

- headache
- increased liver enzyme levels
- muscle pain
- upper respiratory infection
- diarrhea

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

- 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; joint pain; inflammation of the pancreas; nausea; dizziness; tingling sensation; depression; gallstones; 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 have any side effect that bothers you or does not go away.

These are not all the possible side effects of VYTORIN. For more information, ask your doctor or pharmacist.

Call your doctor about medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store VYTORIN?

- Store VYTORIN at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep VYTORIN in its original container until you use it.
- Keep VYTORIN in a tightly closed container, and keep VYTORIN out of light.

Keep VYTORIN and all medicines out of the reach of children.

General Information about the safe and effective use of VYTORIN.

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.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. 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 that you have. It may harm them.

This Patient Information 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.

What are the ingredients in VYTORIN?

Active Ingredients: ezetimibe and simvastatin

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.

This Patient Information has been approved by the U.S. Food and Drug Administration.

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