

Patient Product Information (PPI)
INFORMATION FOR THE PATIENT
ABOUT VYTORIN™

Please read this information carefully before you start to take your medicine, even if you have just refilled your prescription. Some of the information may have changed. You should also read any information provided with other medicines you are currently taking.

Remember that your doctor has prescribed this medicine only for you. Never give it to anyone else.

What is VYTORIN?

VYTORIN (ezetimibe/simvastatin) is a tablet that is available in four strengths:

- VYTORIN 10/10 (ezetimibe 10 mg/simvastatin 10 mg)
- VYTORIN 10/20 (ezetimibe 10 mg/simvastatin 20 mg)
- VYTORIN 10/40 (ezetimibe 10 mg/simvastatin 40 mg)
- VYTORIN 10/80 (ezetimibe 10 mg/simvastatin 80 mg)

Not all presentations/dosage strengths are available.

VYTORIN is a 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. It is used for patients who cannot control their cholesterol levels by diet alone. You should stay on a cholesterol-lowering diet while taking this medicine.

If you have heart disease, VYTORIN reduces the risk of heart attack, stroke, surgery to increase heart blood flow, or hospitalization for chest pain.

How does VYTORIN work?

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.

Product Registrant:

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Why has my doctor prescribed VYTORIN?

Your doctor has prescribed VYTORIN to reduce the amount of cholesterol and triglycerides in your blood. Cholesterol is one of several fatty substances found in the bloodstream. Your total cholesterol is made up mainly of LDL and HDL cholesterol.

LDL cholesterol is often called “bad” cholesterol because it can build up in the walls of your arteries forming plaque. Eventually this plaque build-up can lead to a narrowing of the arteries. This narrowing can slow or block blood flow to vital organs such as the heart and brain. This blocking of blood flow can result in a heart attack or stroke.

HDL cholesterol is often called “good” cholesterol because it helps keep the bad cholesterol from building up in the arteries and protects against heart disease.

Triglycerides are another form of fat in your blood that may increase your risk for heart disease.

How can high cholesterol be treated?

High cholesterol can be treated in two main ways:

Lifestyle Changes – including a cholesterol-lowering diet, increased physical activity, and weight management.

Medication – Cholesterol-lowering medicines are used together with lifestyle changes to help lower cholesterol. Your doctor has prescribed VYTORIN to help lower your cholesterol.

What should I know before and while taking [or using] VYTORIN?

It is important that you continue taking VYTORIN daily as prescribed by your doctor.

Even if you are taking medication to treat high cholesterol, it is important to have your cholesterol measured regularly. You should also know your cholesterol levels and goals.

Use in elderly

No special precautions.

Use in children

VYTORIN is not recommended in children.

Who should not take VYTORIN?

Patients who:

- are hypersensitive (allergic) to ezetimibe, simvastatin, or any of the other ingredients of VYTORIN tablets
- have active liver disease
- are pregnant or breast-feeding

- are taking any of the following medicines:
 - certain antifungal medicines (such as itraconazole, ketoconazole, or posaconazole, or voriconazole)
 - HIV protease inhibitors (such as indinavir, nelfinavir, ritonavir, and saquinavir)
 - certain hepatitis C virus protease inhibitors (such as boceprevir or telaprevir)
 - certain antibiotics (such as erythromycin, clarithromycin, or telithromycin)
 - the 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.

What should I tell my doctor [or pharmacist] before and while taking [or using] VYTORIN?

Tell your doctor about:

Pregnancy: 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 physician immediately.

Breast-feeding: Do not use VYTORIN if you are breast-feeding.

Other Medicines: Talk about any other medicines that you are taking or plan to take. Include those you can get without a prescription.

Medical Problems or Allergies: Talk about any medical problems (including liver disease or liver problems) or allergies you have now or have had in the past.

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 because a different dose may be applicable to you.

Contact your physician promptly if you experience unexplained 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.

- The risk of muscle breakdown is greater at higher doses of VYTORIN, particularly the 10/80 mg dose.
- The risk of muscle breakdown is also greater for older patients (65 years of age and older), female patients, patients with kidney problems, and patients with thyroid problems.

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

Can I take VYTORIN with other medicines or substances?

Because taking VYTORIN with any of the following drugs or substances can increase the risk of muscle problems (see What undesirable effects may VYTORIN have?), it is particularly important to tell your doctor if you are taking:

- antifungal agents (such as itraconazole, posaconazole, ketoconazole or voriconazole)
- HIV protease inhibitors (such as indinavir, nelfinavir, ritonavir, and saquinavir)
- hepatitis C antiviral agents (such as boceprevir, telaprevir, elbasvir, or grazoprevir)
- 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)
- grapefruit juice (which should be avoided while taking VYTORIN)

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 medication used for gout), niacin, or fenofibrate, another fibric acid derivative.

Some of these have already been listed in the above section **Who Should Not Take VYTORIN?**

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

Can I drive or operate machinery while using VYTORIN?

There have been side effects reported with VYTORIN that may affect your ability to drive or operate machinery. Individual responses to VYTORIN may vary (see What undesirable effects may VYTORIN have?).

How should I take VYTORIN?

- Take one VYTORIN 10/10, 10/20, 10/40, or 10/80 tablet by mouth each day, in the evening.
- Because of the increased risk of muscle problems, the VYTORIN 10/80 tablet is only for patients at high risk of heart disease problems who have not reached their cholesterol goal on lower doses.

- Take VYTORIN with or without food.
- If your doctor has prescribed VYTORIN along with cholestyramine (a bile acid sequestrant) or any other bile acid sequestrant, VYTORIN should be taken at least 2 hours before or 4 hours after taking the bile acid sequestrant.
- VYTORIN should be taken as directed by your health care provider. Continue taking your other cholesterol-lowering medicines unless your doctor tells you to stop.

What should I do if I take more VYTORIN than I should?

Take VYTORIN only as prescribed for you. If you take more VYTORIN than you were prescribed, contact your doctor or pharmacist.

What should I do if I miss a dose?

Try to take VYTORIN as prescribed. However, if you miss a dose, just resume the usual schedule of one tablet daily.

What undesirable effects may VYTORIN have?

In clinical studies, VYTORIN was generally well tolerated. The side effects were usually mild, temporary, and similar in type and frequency to side effects in patients who were given ezetimibe alone or simvastatin alone (see What should I tell my doctor [or pharmacist] before and while taking [or using] VYTORIN?).

The following common side effects were reported: muscle aches; elevations in laboratory blood tests of liver (transaminases) and/or muscle (CK) function.

The following uncommon side effects were reported: elevations in blood tests of liver function; elevations in blood uric acid; elevations in the time it takes for blood to clot; protein in urine; weight decreased; dizziness; headache; tingling sensation; abdominal pain; indigestion; flatulence; nausea; vomiting; abdominal bloating; diarrhea; dry mouth; heartburn; rash; itching; hives; joint pain; muscle pain, tenderness, weakness or spasms; neck pain; pain in arms and legs; back pain; unusual tiredness or weakness; feeling tired; chest pain; swelling, especially in the hands and feet; sleep disorder; trouble sleeping.

Additionally, the following side effects have been reported in general use with either VYTORIN, 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, and hives; raised red rash, sometimes with target-shaped lesions; muscle pain, tenderness, or weakness (that in very rare cases may not go away after stopping VYTORIN); alterations in some laboratory blood tests; liver problems (sometimes serious); inflammation of the pancreas; constipation; depression; gallstones; inflammation of the gallbladder; poor memory; memory loss; confusion;

erectile dysfunction; breathing problems including persistent cough and/or shortness of breath or fever.

Contact 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 (symptoms of myasthenia).

Talk to your doctor anytime if you have a medical problem you think may be related to VYTORIN.

If you are prescribed VYTORIN, your healthcare professional may want to conduct routine blood tests to check your liver function before and after starting treatment 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

How can I learn more about VYTORIN and my condition?

You may obtain further information from your doctor or pharmacist.

How long should I keep my medicine?

Do not use this medicine after the date shown following EX (or EXP) on the container.

How should I store VYTORIN?

Please refer to outer carton for storage conditions.
Keep VYTORIN and all medications away from children.

When was this package leaflet last revised?

This package leaflet was last revised in February 2023.

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