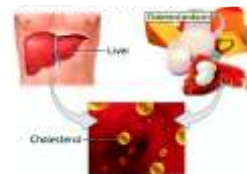
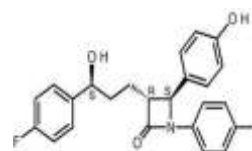


Rx EZETIMIBE

(It is used for treating high levels of cholesterol in the blood)



GENERIC NAME: ezetimibe/simvastatin

DRUG CLASS AND MECHANISM

Vytorin is a combination of ezetimibe (Zetia) and simvastatin (Zocor) that is used for treating high levels of cholesterol in the blood. Vytorin reduces total cholesterol and low density lipoprotein (LDL or "bad") cholesterol while it increases high density lipoprotein (HDL or "good") cholesterol. The ezetimibe component of Vytorin lowers blood cholesterol by blocking the absorption of cholesterol, including dietary cholesterol, from the intestine. It does not affect the absorption of triglycerides. The simvastatin component of Vytorin belongs to a class of drugs called HMG-CoA reductase inhibitors, commonly called "statins." Statins reduce cholesterol by blocking an enzyme in the liver (HMG-CoA reductase) that produces cholesterol. Statins lower total and LDL cholesterol in the blood as well as triglycerides. They also increase HDL cholesterol.

LDL cholesterol is believed to be an important cause of coronary artery disease. Lowering LDL cholesterol levels slows and may even reverse coronary artery disease. Raising HDL cholesterol levels also may slow coronary artery disease. The FDA approved Vytorin in July 2004.

PRESCRIPTION: Yes

PREPARATIONS: Tablets of 10/10, 10/20, 10/40, and 10/80 mg (ezetimibe/simvastatin)

PRESCRIBED FOR

Vytorin is used for reducing total cholesterol, LDL cholesterol and triglycerides, and increasing HDL cholesterol.

DRUG INTERACTIONS

Vytorin contains simvastatin (Zocor), and numerous drugs block the elimination of simvastatin by the liver. Decreased elimination of simvastatin could increase the levels of simvastatin in the body and increase the risk of muscle toxicity from simvastatin. Vytorin should not be combined with drugs that decrease its elimination. Examples of these drugs include erythromycin (E-Mycin), ketoconazole (Nizoral), itraconazole (Sporanox), clarithromycin (Biaxin), telithromycin (Ketek), cyclosporine (Sandimmune), nefazodone (Serzone), and HIV protease inhibitors such as indinavir (Crixivan) and ritonavir (Norvir). Large quantities of grape fruit juice (>1 quart daily) also will increase blood levels of simvastatin.

Amiodarone (Cordarone), verapamil (Calan Verelan, Isoptin), danazol (Danocrine), cyclosporine (Gengraf, Neoral), niacin (Niacor, Niaspan, Slo-Niacin), gemfibrozil (Lopid) and fenofibrate (Tricor) also may increase the risk of muscle toxicity when combined with simvastatin. Patients taking amiodarone or verapamil should not exceed 10/20 mg of Vytorin. Patients taking danazol or cyclosporine should not exceed 10/10 mg of Vytorin.

USES

This medication is a combination of two drugs, ezetimibe and simvastatin. It is used along with a proper diet to help lower bad cholesterol (LDL) and fats (triglycerides) in the blood while raising good cholesterol (HDL). This product is generally prescribed after non-drug treatment (e.g., diet change, increase in exercise, weight loss if overweight) have not been fully successful at lowering cholesterol. Reducing your cholesterol and fats help prevent strokes and heart attacks. Ezetimibe works by reducing the amount of cholesterol your body absorbs from your diet. Simvastatin is an enzyme blocker (HMG-CoA reductase inhibitor), also known as a "statin," which reduces the amount of cholesterol that your body makes normally each day. Simvastatin is used in adults and children (10 years of age and older). Young girls must have had their menstrual periods for at least one year before starting this medication.

HOW TO USE

Take this medication by mouth usually once daily in the evening, with or without food; or as directed by your doctor. Dosage is based on your medical condition, response to therapy, and use of certain interacting medicines. Many of the drugs listed in the Drug Interactions section in this handout may increase the chances of muscle injury when used with simvastatin. Consult your doctor or pharmacist for more details. While being treated with this medication, limit the amount of grapefruit or grapefruit juice you may eat or drink (less than 1 quart a day), unless otherwise directed by your doctor. Grapefruit juice may increase the amount of simvastatin in your bloodstream. Consult your doctor or pharmacist for more details. If you also take certain other drugs to lower your cholesterol (bile acid-binding resins such as

cholestyramine or colestipol), take ezetimibe/simvastatin at least 2 hours before, or at least 4 hours after, these other medications. Use this medication regularly in order to get the most benefit from it. Remember to use it at the same time each day. It may take up to 2 weeks before the full benefit of this drug takes effect. It is important to continue taking this medication even if you feel well. Most people with high cholesterol or fat levels in their blood do not feel sick. Read the Patient Information Leaflet available from your pharmacist. Consult your doctor or pharmacist if you have any questions.

SIDE EFFECTS

The most common side effects of Vytorin are headache, nausea, vomiting, diarrhea, muscle pain, and abnormal liver tests. Hypersensitivity reactions have also been reported. The most serious potential side effects are liver damage and muscle inflammation or breakdown.

The simvastatin component of Vytorin is a statin. Therefore it shares side effects, such as liver and muscle damage associated with statins. Serious liver damage caused by statins is rare. More often, statins cause abnormalities of liver tests, and, therefore, periodic measurement of liver tests in the blood is recommended for all statins. Abnormal tests usually return to normal even if a statin is continued, but if the abnormal test value is greater than three times the upper limit of normal, the statin usually is stopped. Liver tests should be measured before Vytorin is started and periodically thereafter or if there is a medical concern about liver damage. Liver tests should be performed before the 10/80 mg dose of Vytorin is initiated, three months after initiation and then periodically thereafter.

Inflammation of the muscles caused by statins can lead to a serious breakdown of muscle cells called rhabdomyolysis. Rhabdomyolysis causes the release of muscle protein (myoglobin) into the blood. Myoglobin can cause kidney failure and even death. When used alone, statins cause rhabdomyolysis in less than one percent of patients. To prevent the development of rhabdomyolysis, patients taking Vytorin should contact their healthcare provider immediately if they develop unexplained muscle pain, weakness, or muscle tenderness.

DOSING

The recommended dose range of Vytorin is 10/10 mg to 10/80 mg, and it is administered once daily in the evening with or without food. Therapy is usually initiated with 10/20 mg daily, but individuals who need more than a 55% reduction in LDL cholesterol can be started on 10/40 mg daily. Simvastatin increases the effect of warfarin (Coumadin) and the blood concentration of digoxin (Lanoxin). Patients taking simvastatin and warfarin or digoxin should be monitored carefully.

Cholestyramine (Questran) decreases the absorption of ezetimibe (Zetia). Administer Vytorin 2 hours before or at least 4 hours after cholestyramine administration.

OVERDOSE

If overdose is suspected, contact your local poison control center or emergency room immediately. US residents can call the US national poison hotline at 1-800-222-1222. Canadian residents should call their local poison control center directly.

PRECAUTIONS

Before taking ezetimibe/simvastatin, tell your doctor or pharmacist if you think you are allergic to it; or to other drugs called "statins"; or if you have any other allergies. This medication should not be used if you have certain medical conditions. Before using this medicine, consult your doctor or pharmacist if you have: active liver disease. Before using this medication, tell your doctor or pharmacist your medical history, especially of: heart disease, history of liver disease, kidney disease, underactive thyroid (hypothyroidism), poorly controlled diabetes, alcohol use. Developing severe muscle damage, which is rare, can sometimes lead to serious kidney problems (see the Side Effects section in this handout). This medication is usually temporarily stopped if you have any condition which can increase your risk of developing kidney problems. Before you stop taking your medication, notify your doctor immediately if you have any of the following conditions: major surgery, trauma, serious illness (e.g., sepsis or severe metabolic, endocrine, or electrolyte disorders), very low blood pressure, uncontrolled seizures. Limit alcoholic beverages. Daily use of alcohol may increase your chance for serious side effects. Caution is advised when using this drug in the elderly because they may be more sensitive to its side effects, especially muscle damage. This medication must not be used during pregnancy. If you become pregnant or think you may be pregnant, inform your doctor immediately. It is recommended that young girls and women of child-bearing age use effective birth control to prevent pregnancy while taking this

drug. One of these drugs (simvastatin) may cause harm to your unborn child. It is not known if either drug passes into breast milk. A drug similar to simvastatin passes into breast milk, and because of this drug's potential risk of undesirable effects on a nursing infant, breast-feeding is not recommended while using ezetimibe/simvastatin. Consult your doctor before breast-feeding.

MISSED DOSE

If you miss a dose, use it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

STORAGE

Store at room temperature between 68-77 degrees F (20-25 degrees C) away from light and moisture. Do not store in the bathroom. Keep all medicines away from children and pets.

Note : This product information is intended only for residents of the India. Taj Pharmaceuticals Limited, medicines help to treat and prevent a range of conditions—from the most common to the most challenging—for people around the world.



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Revised November 2010