



GENERIC NAME: NIACIN EXTENDED-RELEASE/LOVASTATIN - ORAL
(NVE-uh-sin/LOW-vuh-stat-in)

USES

This combination medication is used along with a proper diet to help lower cholesterol and fats (triglycerides) in the blood. It combines lovastatin (an HMG-CoA reductase inhibitor), also known as a "statin", and niacin which is a B-complex vitamin. In general, this product is prescribed after non-drug treatment options have not been fully successful at lowering cholesterol (e.g., diet change, increase in exercise, weight loss if overweight). Reducing cholesterol and triglycerides help prevent strokes and heart attacks.

HOW TO USE

If you are currently taking a long-acting form of niacin, your doctor can switch you to this combination product after you have reached your proper niacin dosage. If you are currently taking an immediate-release form of niacin, inform your doctor before switching to long-acting niacin. Doses of immediate-release and long-acting niacin are not equal. When switching to long-acting niacin, it is recommended that you use a low dose for several weeks so your body can adjust to the effects. This will also help to reduce the risk of an infrequent but severe liver side effect (fulminant hepatic necrosis). Consult your doctor or pharmacist for details, and follow dosing instructions carefully. Once you have reached your proper dose of long-acting niacin, your doctor may switch you to this combination product. If you have never taken niacin before, you need to first be treated with long-acting niacin (in gradually increasing dosage) before starting this combination lovastatin/niacin product. Take this medication by mouth usually once daily at bedtime with a low-fat snack, or as directed by your doctor. Taking the drug in this manner will increase its absorption and help reduce stomach upset. Swallow this medication whole. Do not crush, chew, or break the medication; this can destroy the long action of the drug and may increase side effects. 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 may increase the chances of muscle injury when used with lovastatin/niacin. Consult your doctor or pharmacist for more details. Avoid eating grapefruit or drinking grapefruit juice while being treated with this medication unless your doctor instructs you otherwise. Grapefruit juice can increase the amount of certain medications 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), allow at least 4 to 6 hours between taking those drugs and this product. Avoid drinking alcohol or hot drinks prior to taking this medicine to reduce the risk of an uncomfortable side effect caused by niacin (flushing). Taking non-enteric coated aspirin or an aspirin-like medication (e.g., NSAIDs like ibuprofen or naproxen) 30 minutes before taking this medicine may help reduce the risk of flushing. Consult your doctor for more information and before taking any aspirin or NSAID product. Do not stop using this medication unless instructed by your doctor. If you have stopped taking niacin for 7 days or more and are resuming treatment, it is recommended that you restart with the lowest dose of this drug before gradually increasing back up to your maintenance dose. Contact your doctor for further instructions. 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 4 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 triglycerides do not feel sick.

SIDE EFFECTS

This medication may cause flushing and a feeling of warmth about the face and neck within the first two hours of taking a dose. These effects may last for one to two hours. Headache, dizziness, a fast heartbeat, redness/itching/tingling of the skin, or swelling of the arms/legs may occur as well. The frequency and intensity of these effects should subside after several weeks as your body adjusts to the medication. Stomach upset, nausea, and diarrhea may also occur. If these effects persist or worsen, notify your doctor or pharmacist promptly. Tell your doctor immediately if any of these unlikely but serious side effects occur: increased thirst, change in the amount of urine, blurred vision, unusual tiredness or fatigue, easy bruising or bleeding. This drug may infrequently cause muscle damage (which can rarely lead to a very serious, possibly fatal, condition called rhabdomyolysis). Seek immediate medical attention if you develop: muscle pain/tenderness/weakness (especially with fever or unusual tiredness). Tell your doctor immediately if any of these highly unlikely but very serious side effects occur: fainting, yellowing eyes and skin, dark urine, severe fatigue, persistent nausea, severe stomach/abdominal pain. A serious allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of a serious allergic reaction include: rash, severe itching, swelling, severe dizziness, trouble breathing. If you notice other effects not listed above, contact your doctor or pharmacist.

PRECAUTIONS

Before taking lovastatin/niacin, tell your doctor or pharmacist if you are allergic to it; or to other "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, active peptic ulcer disease, serious bleeding problems (e.g., arterial bleeding). Before using this medication, tell your doctor or pharmacist your medical history, especially of: heart disease (e.g., unstable angina), kidney disease, history of liver disease, underactive thyroid (hypothyroidism), diabetes, gout, history of stomach/abdominal problems (e.g., ulcers), low phosphate blood levels, alcohol use. The rare development of severe muscle damage (see Side Effects) can infrequently lead to serious kidney problems. This medication is usually temporarily stopped if you have any condition which can increase your risk of developing kidney problems. Before stopping your medication, notify your doctor immediately if you have any of the following conditions: recent or scheduled major surgery, trauma, serious illness (e.g., sepsis, severe metabolic/endocrine/electrolyte disorders), very low blood pressure, uncontrolled seizures. This drug may make you dizzy; use caution engaging in activities requiring alertness such as driving or using machinery. To minimize dizziness and lightheadedness, get up slowly when rising from a seated or lying position. 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 the side effects of the drug, 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 women of child-bearing age use effective birth control measures while taking this drug since lovastatin may cause fetal harm. This medication passes into breast milk and may have undesirable effects on a nursing infant. Breast-feeding is not recommended while using this drug. Consult your doctor before breast-feeding.

DRUG INTERACTIONS

See also the How To Use section. This drug should not be used with the following medications because very serious, possibly fatal interactions may occur: certain azole antifungals (e.g., itraconazole, ketoconazole), delavirdine, HIV protease inhibitors (e.g., ritonavir, amprenavir, lopinavir), certain macrolide antibiotics (e.g., erythromycin, clarithromycin, troleandomycin), mibefradil, nefazodone, telithromycin. If you are currently using any of these medications, tell your doctor or pharmacist before starting this product. Use caution if the following drugs are combined with this medication because serious side effects such as muscle injury (myopathy) infrequently could occur: fibrates (e.g., gemfibrozil, fenofibrate). Even though this product contains niacin, doses of niacin above 1 gram per day infrequently have caused muscle injury (myopathy) with or without lovastatin use. Consult your doctor for more details. Before using this medication, tell your doctor or pharmacist of all prescription and nonprescription/herbal products you may use, especially of: azithromycin, "blood thinners" (e.g., warfarin), cholestyramine, colestipol, drugs for high blood pressure, other niacin and related products (e.g., vitamin products, nicotinamide), other drugs which affect certain liver enzymes (CYP 3A4 substrates, inhibitors, and inducers such as amiodarone, cyclosporine, diltiazem, verapamil, rifampin, St. John's wort, carbamazepine). This product can affect the results of certain lab tests. Make sure laboratory personnel and your doctors know you use this drug. Do not start or stop any medicine without doctor or pharmacist approval.

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. Symptoms of overdose may include: fainting or irregular heartbeat.

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 and 77 degrees F (20 and 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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