**Medication Guide**

**Lovastatin; Niacin extended-release tablets**

**NOTE:** This sheet is a summary. It may not cover all possible information. If you have questions about this medicine talk to your doctor, pharmacist, or health care provider.

**What is this medicine?**

LOVASTATIN; NIAIN (LOE va sta tin; nye a SIN) is used in combination with a healthy diet to lower bad cholesterol and increase good cholesterol.

This medicine may be used for other purposes; ask your health care provider or pharmacist if you have questions.

**How should I use this medicine?**

Take this medicine by mouth with a glass of water. Follow the directions on the prescription label. Swallow whole. Do not crush, break, or chew the tablet. It should be taken in the evening with a low-fat snack. Do not take this medicine with grapefruit juice, hot beverages, or alcohol-containing beverages. Take your doses at regular intervals. Do not take your medicine more often than directed. If you also take cholestyramine or colestipol to lower your cholesterol, you should take this medicine at least 1 hour before or 4 hours after a dose of these medications. If skin flushing (skin warmth, redness) becomes a problem, ask your doctor for advice.

Talk to your pediatrician regarding the use of this medicine in children. Special care may be needed.

Overdosage: If you think you have taken too much of this medicine contact a poison control center or emergency room at once.

**NOTE:** This medicine is only for you. Do not share this medicine with others.

**What if I miss a dose?**

If you miss a dose, take it as soon as you can. If it is almost time for your next dose, take only that dose. Do not take double or extra doses.

**What should I tell my health care provider before I take this medicine?**

They need to know if you have any of these conditions:

- Frequently drink alcoholic beverages
- Kidney or liver disease
- Low blood counts, low platelets, or bleeding problems
- Muscle aches or weakness
- Other medical condition
- Ulcers of intestine or stomach
- An unusual or allergic reaction to lovastatin, niacin, other medicines, foods, dyes, or preservatives
- Pregnant or trying to get pregnant
- Breast-feeding

**What may interact with this medicine?**

Do not take this medicine with any of the following medications:

- Boceprevir
- Certain antibiotics like erythromycin, clarithromycin, and telithromycin
- Certain antiviral medicines for HIV or AIDS
- Medicines for fungal infections like itraconazole, ketoconazole, or posaconazole
- Mifepristone, RU-486
- Nefazodone
- Other niacin products
- Red yeast rice
- Telaprevir
- Telithromycin
- Troleandomycin

This medicine may also interact with the following medications:

- Amiodarone
- Aspirin
- Cholestyramine or colestipol
- Colchicine
- Cyclosporine
- Danazol
- Digoxin
• Grapefruit juice
• Medicines for diabetes
• Medicines for high blood pressure or heart disease
• Nitroglycerin or nitrates like amyl nitrate, isosorbide dinitrate, isosorbide mononitrate
• Other cholesterol medicines like gemfibrozil, fenofibrate or clofibrate
• Ranolazine
• Warfarin

This list may not describe all possible interactions. Give your health care provider a list of all the medicines, herbs, non-prescription drugs, or dietary supplements you use. Also tell them if you smoke, drink alcohol, or use illegal drugs. Some items may interact with your medicine.

What side effects may I notice from receiving this medicine?

Side effects that you should report to your doctor or health care professional as soon as possible:
• Blurred vision
• Breathing problems
• Chest pain or palpitations
• Dark yellow or brown urine
• Decreased urination, difficulty passing urine
• Dizziness that does not go away or fainting spells
• Fever or chills
• Increased blood sugar, especially if you have diabetes
• Nausea, vomiting
• Skin rash, hives, peeling or itching of the skin
• Stomach pain, loss of appetite
• Swelling of the body (legs, ankles, arms)
• Unexplained muscle pain, tenderness, cramps, or weakness
• Unusual or severe tiredness or weakness
• Yellowing of the skin or eyes

Side effects that usually do not require medical attention (report to your doctor or health care professional if they continue or are bothersome):
• Decreased sexual function or desire
• Diarrhea or constipation
• Flushing, warmth, and burning or tingling of the skin
• Headache
• Stomach upset, discomfort, or bloating

This list may not describe all possible side effects. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

What should I watch for while using this medicine?

Visit your doctor or health care professional for regular checks on your progress. You will need to have regular tests to make sure your liver is working properly.

This medicine is only part of a total cholesterol-lowering program. Your physician or dietician can suggest a low-cholesterol and low-fat diet that will reduce your risk of getting heart and blood vessel disease. Avoid alcohol and smoking, and keep a proper exercise schedule.

Do not use this drug if you are pregnant or breast-feeding. Serious side effects to an unborn child or to an infant are possible. Talk to your doctor or pharmacist for more information.

Tell your doctor or health care professional as soon as you can if you get any unexplained muscle pain, tenderness, or weakness, especially if you also have a fever and tiredness. Your doctor or health care professional may tell you to stop taking this medicine if you develop muscle problems. If your muscle problems do not go away after stopping this medicine, contact your health care professional.

This medicine may affect blood sugar levels. If you have diabetes, check with your doctor or health care professional before you change your diet or the dose of your diabetic medicine.

You may get drowsy or dizzy. Do not drive, use machinery, or do anything that needs mental alertness until you know how this drug affects you. Do not stand or sit up quickly, especially if you are an older patient. This reduces the risk of dizzy or fainting spells.

Do not drink hot drinks or alcohol at the same time you take your medicine. Hot drinks and alcohol can increase the flushing caused by niacin, which can be uncomfortable. Alcohol also can increase possible dizziness.

If you are going to have surgery tell your doctor or health care professional that you are taking this medicine.

You may notice the empty shell of the tablet in your stool. This is no cause for concern.

Where should I keep my medicine?

Keep out of the reach of children.

Store at room temperature between 20 and 25 degrees C (68 and 77 degrees F). Throw away any unused medicine after the expiration date.
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