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PATIENT INFORMATION

Niacin (NYE-a-sin) Extended-release Tablets USP for oral use Rx only

Read this information carefully before you start taking niacin extended-release tablets 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.

What is niacin extended-release tablet?

Niacin extended-release tablet is a prescription medicine used with diet and exercise to increase the good cholesterol (HDL) and lower the bad cholesterol (LDL) and fats (triglycerides) in your blood.

- Niacin extended-release tablet is also used to lower the risk of heart attack in people who have had a heart attack and have high cholesterol.
- In people with coronary artery disease and high cholesterol, niacin extended-release tablets, when used with a bile acid-binding resin (another cholesterol medicine) can slow down or lessen the build-up of plaque (fatty deposits) in your arteries.
- In people with heart problems and well-controlled cholesterol, taking niacin extended-release tablets with another cholesterol-lowering medicine (simvastatin) does not reduce heart attacks or strokes more than taking simvastatin alone.

It is not known if niacin extended-release tablet is safe and effective in children 16 years of age and under.

Who should not take niacin extended-release tablets?

Do not take niacin extended-release tablets if you have:

- liver problems.
- a stomach ulcer.
- bleeding problems.
- an allergy to niacin or any of the ingredients in niacin extended-release tablets. See the end of this Patient Information Leaflet for a complete list of ingredients in niacin extended-release tablets.

What should I tell my doctor before taking niacin extended-release tablets?

Before you take niacin extended-release tablets, tell your doctor about all your medical problems including, if you:

- have diabetes. Tell your doctor if your blood sugar levels change after you take niacin extended-release tablets.
- have gout.
- have kidney problems.
- are pregnant or plan to become pregnant. It is not known if niacin extended-release tablets will harm your unborn baby. Talk to your doctor if you are pregnant or plan to become pregnant while taking niacin extended-release tablets.
- are breastfeeding or plan to breastfeed. Niacin can pass into your breast milk. You and your doctor should decide if you will take niacin extended-release tablets or breastfeed. You should not do both. Talk to your doctor about the best way to feed your baby if you take niacin extended-release tablets.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, herbal supplements or other nutritional supplements containing niacin or nicotinamide. Niacin extended-release tablets and other medicines may affect each other causing side effects. Niacin extended-release tablets may affect the way other medicines work, and other medicines may affect how niacin extended-release tablets works.

Especially tell your doctor if you take:

- other medicines to lower cholesterol or triglycerides
- aspirin
- blood pressure medicines
- blood thinner medicines
- large amounts of alcohol

Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

How should I take niacin extended-release tablets?

- Take niacin extended-release tablets exactly as your doctor tells you to take it.
- Take niacin extended-release tablets whole. Do not break, crush or chew niacin extended-release tablets before swallowing.
- Take niacin extended-release tablets 1 time a day at bedtime after a low-fat snack. Niacin extended-release tablets should not be taken on an empty stomach.
- All forms of niacin are not the same as niacin extended-release tablets. Do not switch between forms of niacin without first talking to your doctor as severe liver damage can occur.
- Do not change your dose or stop taking niacin extended-release tablets unless your doctor tells you to.
- If you need to stop taking niacin extended-release tablets, call your doctor before you start taking niacin extended-release tablets again. Your doctor may need to lower your dose of niacin extended-release tablets.
- If you take too much niacin extended-release tablets, call your doctor right away.
- Patients receiving niacin extended-release tablets may notice an inert matrix tablet passing in the stool. Patients should be informed that the active medication has already been absorbed by the time the patient sees the inert matrix tablet.
- Medicines used to lower your cholesterol called bile acid resins, such as colestipol and cholestyramine, should not be taken at the same time of day as niacin extended-release tablets. You should take niacin extended-release tablets and the bile acid resin medicine at least 4 to 6 hours apart.
- Your doctor may do blood tests before you start taking niacin extended-release tablets and during your treatment. You should see your doctor regularly to check your cholesterol and triglyceride levels and to check for side effects.

What are the possible side effects of niacin extended-release tablets?

Niacin extended-release tablets may cause serious side effects, including:

- **unexplained muscle pain, tenderness or weakness**
- **severe liver problems. Signs of liver problems include:**
 - increased tiredness
 - dark colored urine (tea-colored)
 - loss of appetite

- light colored stools
- nausea
- right upper stomach (abdomen) pain
- yellowing of your skin or whites of your eye
- itchy skin
- **high blood sugar level (glucose)**

Call your doctor right away if you have any of the side effects listed above.

The most common side effects of niacin extended-release tablets include:

- flushing
- diarrhea
- nausea
- vomiting
- increased cough
- rash
- itching

Flushing is the most common side effect of niacin extended-release tablets. Flushing happens when tiny blood vessels near the surface of the skin (especially on the face, neck, chest and/or back) open wider. Symptoms of flushing may include any or all of the following:

- warmth
- redness
- itching
- tingling of the skin

Flushing does not always happen. If it does, it is usually within 2 to 4 hours after taking a dose of niacin extended-release tablets. Flushing may last for a few hours. Flushing is more likely to happen when you first start taking niacin extended-release tablets or when your dose of niacin extended-release tablets is increased. Flushing may get better after several weeks.

If you wake up at night because of flushing, get up slowly, especially if you:

- feel dizzy or faint
- take blood pressure medicines

To lower your chance of flushing:

- Ask your doctor if you can take aspirin to help lower the flushing side effect from niacin extended-release tablets. You can take aspirin (up to the recommended dose of 325 mg) about 30 minutes before you take niacin extended-release tablets to help lower the flushing side effect.
- Do not drink hot beverages (including coffee), alcohol, or eat spicy foods around the time you take niacin extended-release tablets.
- Take niacin extended-release tablets with a low-fat snack to lessen upset stomach.

People with high cholesterol and heart disease are at risk for a heart attack. Symptoms of a heart attack may be different from a flushing reaction from niacin extended-release tablets. **The following may be symptoms of a heart attack due to heart disease and not a flushing reaction:**

- chest pain
- pain in other areas of your upper body such as one or both arms, back, neck, jaw or stomach
- shortness of breath

- sweating
- nausea
- lightheadedness

The chest pain you have with a heart attack may feel like uncomfortable pressure, squeezing, fullness or pain that lasts more than a few minutes, or that goes away and comes back. Heart attacks may be sudden and intense, but often start slowly, with mild pain or discomfort.

Call your doctor right away if you have any symptoms of a heart attack.

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 niacin extended-release tablets. For more information, ask your doctor or pharmacist.

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

How should I store niacin extended-release tablets?

Store niacin extended-release tablets at room temperature between 68°F to 77°F (20°C to 25°C).

Keep niacin extended-release tablets and all medicines out of the reach of children.

General information about the safe and effective use of niacin extended-release tablets.

Medicines are sometimes prescribed for purposes other than those listed in a patient information leaflet. Do not use niacin extended-release tablets for a condition for which it was not prescribed. Do not give niacin extended-release tablets to other people, even if they have the same symptoms that you have. It may harm them.

This Patient Information Leaflet summarizes the most important information about niacin extended-release tablets. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about niacin extended-release tablets that is written for health professionals.

For more information, call our toll-free number, 1-800-399-2561, visit our website at www.lupinpharmaceuticals.com.

What are the ingredients in niacin extended-release tablets?

Active ingredient: niacin

Inactive Ingredients: colloidal silicon dioxide, hypromellose, microcrystalline cellulose, povidone, polyethylene glycol, stearic acid, and the following coloring agents: iron oxide red, iron oxide yellow, FD&C yellow #6/sunset yellow FCF aluminum lake, polyethylene glycol and titanium dioxide.

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

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