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Lovastatin/niacin

Niacin and Iovastatin (Oral)

Generic name: niacin and lovastatin [NYE-a-sin, loe-va-STAT-in]

Brand name: Advicor

Drug class: Antihyperlipidemic combinations

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Uses for niacin and lovastatin

Niacin and lovastatin combination is used together with a proper diet to help lower cholesterol and triglyceride (fat) levels in the blood. This medicine may help prevent medical problems (eg, heart attacks, stroke) that are caused by fat clogging the blood vessels.

Niacin and lovastatin combination medicine is a combination of two drugs that work together to lower cholesterol and lipid (fat) disorders. Niacin is vitamin B3, which reduces the amount of cholesterol in the blood. Lovastatin belongs to the group of medicines called HMG-CoA reductase inhibitors, or statins. It works to reduce the amount of cholesterol in the blood by blocking an enzyme that is needed to make cholesterol.

This medicine was available only with your doctor's prescription. The Advicor(R) product will no longer be marketed in the United States as of April 18, 2016.

Before using niacin and lovastatin

In deciding to use a medicine, the risks of taking the medicine must be weighed against the good it will do. This is a decision you and your doctor will make. For this medicine, the following should be considered:

Allergies

Tell your doctor if you have ever had any unusual or allergic reaction to this medicine or any other medicines. Also tell your health care professional if you have any other types of allergies, such as to foods, dyes, preservatives, or animals. For non-prescription products, read the label or package ingredients carefully.

Pediatric

The use of niacin and lovastatin combination is not recommended in children.

Geriatric

Appropriate studies performed to date have not demonstrated geriatric-specific problems that would limit the usefulness of niacin and lovastatin combination in the elderly.

Breast Feeding

Studies in women breastfeeding have demonstrated harmful infant effects. An alternative to this medication should be prescribed or you should stop breastfeeding while using this medicine.

Interactions with Medicines

Although certain medicines should not be used together at all, in other cases two different medicines may be used together even if an interaction might occur. In these cases, your doctor may want to change the dose, or other precautions may be necessary. When you are taking this medicine, it is especially important that your healthcare professional know if you are taking any of the medicines listed below. The following interactions have been selected on the basis of their potential significance and are not necessarily all-inclusive.

Using this medicine with any of the following medicines is not recommended. Your doctor may decide not to treat you with this medication or change some of the other medicines you take.



- Atazanavir
- Boceprevir
- Clarithromycin
- Cobicistat
- Darunavir
- Erythromycin
- Fosamprenavir
- Idelalisib
- Indinavir
- Itraconazole
- Ketoconazole
- Levoketoconazole
- Lopinavir
- Mibefradil
- Mifepristone
- Nefazodone
- Nelfinavir
- Nirmatrelvir
- Posaconazole
- Ritonavir
- Saquinavir
- Telaprevir

• Telithromycin • Tipranavir Voriconazole Using this medicine with any of the following medicines is usually not recommended, but may be required in some cases. If both medicines are prescribed together, your doctor may change the dose or how often you use one or both of the medicines. Adagrasib Amiodarone Atorvastatin • Belzutifan Bezafibrate • Ceritinib Cerivastatin Ciprofibrate • Clofibrate • Colchicine Conivaptan • Cyclosporine • Dabigatran Etexilate Dabrafenib • Dalfopristin

• Danazol

• Daptomycin

Delavirdine

• Diltiazem

Duvelisib

Fedratinib

Fenofibrate

• Fenofibric Acid

Fexinidazole

• Fluconazole

Fosnetupitant

• Dronedarone

Gemfibrozil
Glecaprevir
• Ivosidenib
Larotrectinib
Lefamulin
Lenacapavir
• Letermovir
Levoketoconazole
Lomitapide
Lorlatinib
• Lovastatin
• Lumacaftor
Mavacamten
Methotrexate
Netupitant
• Niacin
Olutasidenib
Omaveloxolone
Pacritinib
Phenobarbital
Pibrentasvir
Pirtobrutinib
Pitavastatin
Primidone
Quinupristin
Ranolazine
Ritlecitinib
Rosuvastatin
Simvastatin
Tocilizumab
Trofinetide
Verapamil
Using this medicine with any of the following medicines may cause an increased risk of certain side effects, but using both drugs may be the best treatment for you. If both medicines are prescribed together, your doctor may change the

dose or how often you use one or both of the medicines.

- Azithromycin
- Bosentan
- Clopidogrel
- Oat Bran
- Pectin
- · St John's Wort
- Warfarin

Interactions with Food/Tobacco/Alcohol

Certain medicines should not be used at or around the time of eating food or eating certain types of food since interactions may occur. Using alcohol or tobacco with certain medicines may also cause interactions to occur. The following interactions have been selected on the basis of their potential significance and are not necessarily all-inclusive.

Using this medicine with any of the following is usually not recommended, but may be unavoidable in some cases. If used together, your doctor may change the dose or how often you use this medicine, or give you special instructions about the use of food, alcohol, or tobacco.

· Grapefruit Juice

Using this medicine with any of the following may cause an increased risk of certain side effects but may be unavoidable in some cases. If used together, your doctor may change the dose or how often you use this medicine, or give you special instructions about the use of food, alcohol, or tobacco.

Ethanol

Other Medical Problems

The presence of other medical problems may affect the use of this medicine. Make sure you tell your doctor if you have any other medical problems, especially:

- · Alcohol abuse, or history of or
- Liver disease, history of—Use with caution. May cause side effects to become worse.
- Angina (severe chest pain), unstable or
- · Diabetes or
- · Gout or
- Heart attack, acute—Use with caution. May make these conditions worse.
- Bleeding, arterial (coming from an artery) or
- Liver disease, active or
- · Liver enzymes, elevated or
- Peptic ulcer disease, active—Should not be used in patients with these conditions.

- · Electrolyte disorders, severe or
- · Endocrine disorders, severe or
- · Epilepsy (seizures), not well-controlled or
- · Hypotension (low blood pressure) or
- · Metabolic disorders, severe or
- Sepsis (severe infection in the blood)—Patients with these conditions may be at risk of developing muscle and kidney problems.
- Kidney disease—Use with caution. The effects this medicine may be increased because of slower removal of the medicine from the body.

Proper use of niacin and lovastatin

Take this medicine only as directed by your doctor. Do not take more or less of it and do not take it more often or for a longer time than your doctor ordered. Also, this medicine works best if there is a constant amount in the blood. To help keep this amount constant, do not miss any doses and take the medicine at the same time each day.

In addition to this medicine, your doctor may change your diet to one that is low in fat, sugar, and cholesterol. *Carefully follow your doctor's orders about any special diet*.

Swallow the extended-release tablet whole. Do not break, crush, or chew it.

It is best to take this medicine at bedtime, with a low-fat meal or snack. Do not take it on an empty stomach.

If you are taking danazol (Danocrine®), diltiazem (Cardizem®), or verapamil (Calan®, Isoptin®, Verelan®) together with lovastatin, your lovastatin dose should not be higher than 20 milligrams (mg) per day, unless otherwise directed by your doctor. Do not use more than 40 mg per day of lovastatin together with amiodarone (Cordarone®). When used together with higher doses of lovastatin, these medicines may increase your risk of muscle injury and could result in kidney problems.

Tell your doctor if you regularly drink grapefruit juice. Drinking large amounts of grapefruit juice (more than 1 quart each day) while taking this medicine may increase your risk of muscle injury and could result in kidney problems.

Do not drink large amounts of alcohol with lovastatin. This could cause liver injury.

Dosing

The dose of this medicine will be different for different patients. Follow your doctor's orders or the directions on the label. The following information includes only the average doses of this medicine. If your dose is different, do not change it unless your doctor tells you to do so.

The amount of medicine that you take depends on the strength of the medicine. Also, the number of doses you take each day, the time allowed between doses, and the length of time you take the medicine depend on the medical problem for which you are using the medicine.

- For oral dosage form (extended-release tablets):
 - · For high cholesterol:

- Adults—At first, 500 milligrams (mg) of niacin and 20 mg of lovastatin (combined in one tablet) once a day, at bedtime. Your doctor may adjust your dose as needed. However, the dose is usually not more than 2000 mg of niacin and 40 mg of lovastatin per day.
- Children—Use is not recommended.

Missed Dose

If you miss a dose of this medicine, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not double doses.

If you have not taken this medicine for more than 7 days, check with your doctor. You may need to have your dose reduced before you can start taking this medicine again.

Storage

Store the medicine in a closed container at room temperature, away from heat, moisture, and direct light. Keep from freezing.

Keep out of the reach of children.

Do not keep outdated medicine or medicine no longer needed.

Ask your healthcare professional how you should dispose of any medicine you do not use.

Detailed Lovastatin / niacin dosage information

Precautions while using niacin and lovastatin

It is important that your doctor check your progress at regular visits to make sure that this medicine is working properly to lower your cholesterol and triglyceride (fats) levels. Blood tests may be needed to check for unwanted effects.

Using this medicine while you are pregnant can harm your unborn baby. Use an effective form of birth control to keep from getting pregnant. If you think you have become pregnant while using the medicine, tell your doctor right away.

Do not use lovastatin/niacin if you are also using the following medicines: boceprevir (Victrelis®), nefazodone (Serzone®), telaprevir (Incivek®), certain antibiotics (such as clarithromycin, erythromycin, itraconazole, ketoconazole, posaconazole, telithromycin, Nizoral®), or certain medicines to treat HIV/AIDS (such as atazanavir, indinavir, nelfinavir, ritonavir, saquinavir, Crixivan®, Kaletra®, Lexiva®, Norvir®, Prezista®, Reyataz®). *Using these medicines together can cause serious side effects*.

Call your doctor right away if you have unexplained muscle pain, tenderness, or weakness. These may be symptoms of serious muscle problems such as myopathy or immune-mediated necrotizing myopathy (IMNM).

Call your doctor right away if you have dark-colored urine, have a fever, have muscle cramps or spasms, have muscle pain or stiffness, feel very tired or weak, or have diarrhea. These could be symptoms of a serious muscle problem called rhabdomyolysis, which can cause kidney problems.

Stop using this medicine and check with your doctor right away if you have pain or tenderness in the upper stomach, pale stools, dark urine, loss of appetite, nausea, unusual tiredness or weakness, or yellow eyes or skin. These could be symptoms of liver damage.

This medicine may affect blood sugar levels. This is important if you are diabetic or prediabetic. If you notice a change in the results of your blood or urine sugar tests or if you have any questions, check with your doctor.

This medicine may cause some people to become dizzy, lightheaded, drowsy, or less alert than they are normally. *Make* sure you know how you react to this medicine before you drive, use machines, or do anything else that could be dangerous if you are dizzy or not alert. Change positions slowly when getting up from a sitting or lying position.

This medicine should not be taken with vitamins containing niacin or nicotinamide.

Make sure any doctor or dentist who treats you knows that you are using this medicine. You may need to stop using this medicine if you have major surgery, a major injury, or you develop other serious health problems. It may also affect the result of certain medical tests.

This medicine may cause a side effect called flushing. Flushing is a feeling of warmth or redness on the face, neck, arms, and occasionally, on the upper chest. To avoid flushing, alcohol, hot beverages, and spicy foods should be avoided around the time you take this medicine. Additionally, your doctor may recommend that you take aspirin 30 minutes before taking this medicine to prevent flushing.

Do not take other medicines unless they have been discussed with your doctor. This includes prescription or nonprescription (over-the-counter [OTC]) medicines and herbal or vitamin supplements.

Side Effects of niacin and lovastatin

Along with its needed effects, a medicine may cause some unwanted effects. Although not all of these side effects may occur, if they do occur they may need medical attention.

Check with your doctor immediately if any of the following side effects occur:

More common

- · Cough or hoarseness
- · feeling of warmth
- · fever or chills
- lower back or side pain
- pain
- · painful or difficult urination
- redness, itching, or tingling of the face, neck, arms, and occasionally, upper chest

Less common

- Abdominal or stomach pain
- blurred vision
- · cramping pain or stiffness
- · difficulty moving
- · dry mouth
- · dry skin

- · fruit-like breath odor
- · increased hunger
- · increased thirst
- · increased urination
- joint pain
- muscle aches, weakness, tenderness, or pain
- nausea
- swollen joints
- · unexplained weight loss
- unusual tiredness or weakness
- vomiting

Rare

- · Dark-colored urine
- muscle cramps, pain, spasm, or stiffness

Some side effects may occur that usually do not need medical attention. These side effects may go away during treatment as your body adjusts to the medicine. Also, your health care professional may be able to tell you about ways to prevent or reduce some of these side effects. Check with your health care professional if any of the following side effects continue or are bothersome or if you have any questions about them:

More common

- Diarrhea
- · general feeling of discomfort or illness
- headache
- itching skin
- · loss of appetite
- nausea
- rash
- runny nose
- shivering
- · shortness of breath
- · sore throat
- sweating
- trouble sleeping

Less common

- · Acid or sour stomach
- belching
- heartburn
- indigestion
- · lack or loss of strength
- · stomach discomfort or upset

Other side effects not listed may also occur in some patients. If you notice any other effects, check with your healthcare professional.

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

1 Lovastatin / niacin side effects (more detail)

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Commonly used brand name(s)

In the U.S.

Advicor

Pharmacologic Class: Vitamin B (class)

Chemical Class: Nicotinic Acid (class)

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- · Check interactions
- · Compare alternatives
- Reviews (1)
- Side effects
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Advicor

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circumstances.

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DRUG STATUS

Availability



Discontinued

Pregnancy & Lactation



Risk data available

CSA Schedule*

N/A Not a controlled drug

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Advicor (lovastatin / niacin) 20 mg-500 mg (a 502)





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