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Niacin/simvastatin

Simvastatin and niacin (Oral)

Generic name: simvastatin and niacin [sim-va-STAT-in, NYE-a-sin]

Brand name: Simcor

Drug class: Antihyperlipidemic combinations

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Uses Before taking Dosage Warnings Side effects Brand names

Uses for simvastatin and niacin

Simvastatin and niacin combination is used together with a proper diet to lower cholesterol and triglyceride (fat) levels in the blood. This medicine may help prevent medical problems caused by clogged blood vessels, such as heart attacks and strokes.

Simvastatin and niacin work together to treat cholesterol and lipid (fat) disorders. Niacin is vitamin B3, which reduces the amount of cholesterol in the blood. Simvastatin belongs to the group of medicines called HMG-CoA 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 Simcor(R) product will no longer be marketed in the United States as of April 18, 2016.

Before using simvastatin and niacin

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

Appropriate studies have not been performed on the relationship of age to the effects of simvastatin and niacin combination in the pediatric population. Safety and efficacy have not been established.

Geriatric

Appropriate studies performed to date have not demonstrated geriatric-specific problems that would limit the usefulness of simvastatin and niacin combination in the elderly. However, elderly patients are more likely to have muscle problems,

which may require caution in patients receiving this medicine.

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.

- Amprenavir
- Atazanavir
- Boceprevir
- Clarithromycin
- Cobicistat
- Cyclosporine
- Danazol
- Darunavir
- Erythromycin
- Fosamprenavir
- Gemfibrozil
- Idelalisib
- Indinavir
- Itraconazole
- Ketoconazole
- Letermovir
- Levoketoconazole
- Lopinavir
- Mibefradil
- Mifepristone
- Nefazodone
- Nelfinavir

Paritaprevir
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.
Acenocoumarol
Adagrasib
Amiodarone
Amlodipine
Atorvastatin
Azithromycin
Belzutifan
Bempedoic Acid
Bezafibrate
Carbamazepine
Ceritinib
Cerivastatin
Ciprofibrate
Ciprofloxacin
Clofibrate
• Colchicine
Conivaptan
Dabigatran Etexilate
Dabrafenib
Dalfopristin
Daptomycin
Darolutamide

• Nirmatrelvir

- Delavirdine
 Digoxin
 Diltiazem
 Dronedarone
 Duvelisib
 Elexacaftor
 Eltrombopag
 Enasidenib
 Encorafenib
 Eslicarbazepine Acetate
- Fenofibrate

Fenofibric Acid

Fedratinib

- Fexinidazole
- Fluconazole
- Fosnetupitant
- Fusidic Acid
- Glecaprevir
- Ivosidenib
- Larotrectinib
- Lefamulin
- Leflunomide
- Lenacapavir
- Leniolisib
- Levamlodipine
- Levoketoconazole
- Lomitapide
- Lorlatinib
- Lovastatin
- Lumacaftor
- Mavacamten
- Methotrexate
- Midostaurin
- Momelotinib

Netupitant
• Niacin
Olutasidenib
Omaveloxolone
Pacritinib
Pazopanib
Phenobarbital
Pibrentasvir
Pirtobrutinib
Pitavastatin
Primidone
Quinupristin
Ranolazine
Ribociclib
Risperidone
Ritlecitinib
Rosuvastatin
Simeprevir
Simvastatin
Tadalafil
Teriflunomide
Tocilizumab
Trofinetide
Verapamil
Warfarin
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.
Albiglutide
Alitretinoin
Bosentan
Cilostazol

• Clopidogrel

- Efavirenz
- Fosphenytoin
- Fostemsavir
- Interferon Beta
- Levothyroxine
- Oat Bran
- Oxcarbazepine
- Pectin
- Phenytoin
- Rifampin
- St John's Wort
- Ticagrelor
- 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.

- Cranberry Juice
- · 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
- · Chinese ancestry or
- Hypothyroidism (an underactive thyroid), not well-controlled or
- · Kidney disease, severe or
- Liver disease, history of—Use with caution. May cause side effects to become 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.
- Dehydration or
- · Electrolyte disorders, severe or
- Endocrine disorders, severe or
- · Epilepsy (seizures), not well-controlled or
- · Hypotension (low blood pressure) or
- · Major surgery or trauma, recent or
- · Metabolic disorders, severe or
- Sepsis (severe infection in the blood)—Patients with these conditions may be at risk for muscle or kidney problems.
- Diabetes—This medicine may increase blood sugar levels.
- Gout—Use with caution. May make this condition worse.

Proper use of simvastatin and niacin

Take this medicine only as directed by your doctor. Do not use more of it, do not use it more often, and do not use it for a longer time than your doctor ordered.

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 change your dose without checking first with your doctor. The 80 mg dose of simvastatin may increase your risk to have serious muscle problems.

If you are taking amiodarone (Cordarone®), amlodipine (Norvasc®), or ranolazine (Ranexa®) together with niacin/simvastatin, your niacin/simvastatin dose should not exceed 1000 mg/20 mg per day, unless directed otherwise by your doctor. When used together, these medicines may increase your risk of muscle injury which can lead to kidney failure, particularly at higher doses of simvastatin.

If you are also using cholestyramine (Questran®) or colestipol (Colestid®), take it at least 4 to 6 hours before or after you take this medicine.

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 the amount of simvastatin in the body which may increase your risk of muscle injury and could result in kidney failure.

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:
 - For patients not on niacin or simvastatin therapy:
 - Adults—One tablet once a day in the evening. Your doctor may adjust your dose if needed. However, the dose is usually not more than 2000 milligrams (mg) of niacin and 40 mg of simvastatin.
 - Children—Use and dose must be determined by your doctor.
 - For patients on niacin therapy:
 - Adults—One tablet (500 milligrams [mg] of niacin and 20 mg of simvastatin) once a day in the evening. Your doctor may adjust your dose if needed. However, the dose is usually not more than 2000 mg of niacin and 40 mg of simvastatin.
 - Children—Use and dose must be determined by your doctor.
 - For patients on simvastatin therapy:
 - Adults—One tablet (500 milligrams [mg] of niacin and 40 mg of simvastatin) once a day in the evening. Your doctor may adjust your dose if needed. However, the dose is usually not more than 2000 mg of niacin and 40 mg of simvastatin.
 - Children—Use and dose must be determined by your doctor.

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.

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 Niacin / simvastatin dosage information

Precautions while using simvastatin and niacin

It is very important that your doctor check your progress at regular visits to make sure that this medicine is working properly. 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 niacin/simvastatin if you are also using the following medicines: boceprevir (Victrelis®), cyclosporine (Gengraf®, Neoral®, Sandimmune®), danazol (Danocrine®), gemfibrozil (Lopid®), nefazodone (Serzone®), telaprevir (Incivek®), certain antibiotics (such as clarithromycin, erythromycin, itraconazole, ketoconazole, posaconazole, telithromycin, Nizoral®), certain blood pressure medicines (such as diltiazem, verapamil, Calan®, Cardizem®, Verelan®), 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). Myopathy is more common when high doses of simvastatin (e.g., 80 milligrams) are used, but some people get myopathy with lower doses.

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

Chinese patients who are taking large amounts of niacin (greater than or equal to 1 gram or 1000 milligrams per day) together with simvastatin may have an increased risk for muscle injury. Talk to your doctor if you are Chinese or have Chinese ancestry and take large amounts of niacin (Niacor®, Niaspan®). Your doses of niacin/simvastatin should not be more than 1000 mg/20 mg per day.

Make sure your doctor or dentist knows that you are using this medicine. Stop using this medicine several days before having surgery or medical tests. This medicine may affect the results of certain medical tests. You may also need to stop using this medicine if you have a major surgery, a major injury, or you develop other serious health problems.

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 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.

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 simvastatin and niacin

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:

Incidence not known

- · Abdominal or stomach pain, severe
- · black, tarry stools
- chills
- dark-colored urine
- dizziness
- fever
- headache
- · light-colored stools
- · loss of appetite
- muscle cramps or spasms
- · muscle pain or stiffness
- muscular tenderness, wasting, or weakness
- · nausea or vomiting
- rash
- · unpleasant breath odor
- unusual tiredness or weakness
- · vomiting of blood
- · yellow eyes or skin

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

- · Feeling of warmth
- redness of the face, neck, arms, and occasionally, upper chest

Less common

- · Back pain
- diarrhea

· itching skin

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 Niacin / simvastatin side effects (more detail)

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Commonly used brand name(s)

In the U.S.

Simcor

Pharmacologic Class: HMG-COA Reductase Inhibitor

Chemical Class: Nicotinic Acid (class)

More about niacin / simvastatin

- · Check interactions
- Compare alternatives
- Reviews (8)
- · Side effects
- Dosage information

- During pregnancy
- · Drug class: antihyperlipidemic combinations

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Other brands

Simcor

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Other brands

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Related treatment guides

- Hyperlipoproteinemia Type IIb, Elevated LDL VLDL
- Hyperlipoproteinemia Type IIa, Elevated LDL
- High Cholesterol
- Hyperlipoproteinemia
- Hyperlipoproteinemia Type IV, Elevated VLDL

Further information

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

Medical Disclaimer

DRUG STATUS

Availability



Pregnancy & Lactation

& Risk data available

CSA Schedule*

N/A Not a controlled drug

User Reviews & Ratings

6.8 / 10

8 Reviews

Images

Simcor (niacin / simvastatin) 1000 mg / 40 mg (a 1000-40)



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