



*****FDA DRUG SAFETY COMMUNICATION and HEALTH ALERT*****

Zocor (simvastatin): Label Change - New Restrictions, Contraindications, and Dose Limitations

If you are a patient taking a medication (including **Simvastatin, Vytorin, Zocor or Simcor**) that has recently had its prescribing information revised, it may be necessary for you to schedule an appointment with your healthcare provider.

Please review the below information. If the below information applies to you, please contact our office to schedule an appointment to review your medication care plan.

Patients affected by the changes to the prescribing recommendations for Simvastatin (Zocor), Vytorin and Simcor:

Some people taking these medications will be affected and other will not. Changes to the prescribing recommendations affect:

- People who take the highest dose (80mg) of any of the following: Simvastatin, Vytorin, Zocor, or Simcor. This dose should only be used by people who have been taking them chronically (such as 12 months or more) without having muscle damage. There is an increased risk of muscle damage with the highest dose, especially during the first year of use.
- People who take Simvastatin, Vytorin, Zocor, or Simcor at any dose who also take certain other medications that can increase the risk of muscle problems. See *“What medications cannot be taken with any dose of Simvastatin, Vytorin, Zocor, or Simcor?”* and *“What other medications or substances might affect my prescription for Simvastatin, Vytorin, Zocor, or Simcor?”*

Other people are not affected by these changes to the prescribing recommendations.

For more information about the risk of muscle problems, please read *“What are the muscle problems associated with Simvastatin, Vytorin, Zocor, or Simcor?”*

I currently take Simvastatin, Vytorin, Zocor, or Simcor and think the changes to the prescribing recommendations might affect me. What should I do?

If you think you may be affected by these changes, talk to your doctor. Your doctor will determine whether you are affected by these changes or not. You should talk to your doctor before you stop taking any medications.

Tell your doctor about all the medications you take, including any prescription and nonprescription medications, vitamins, and herbal supplements. This will help your doctor decide if changes should be made to any of the medications you may be taking.

If your doctor decides that your current dose of Simvastatin, Vytorin, Zocor, or Simcor is still right for you, continue to take your medication as prescribed.

What medications cannot be taken with ANY dose of Simvastatin, Vytorin, Zocor, or Simcor?

Do not take Simvastatin, Vytorin, Zocor, or Simcor if you also take:

- Certain antifungal medicines, including itraconazole, ketoconazole, or posaconazole.
- HIV protease inhibitors (indinavir, nelfinavir, ritonavir, saquinavir, tipranavir, or atazanavir).
- Certain antibiotics, including erythromycin, clarithromycin, or telithromycin.
- Nefazodone
- Gemfibrozil, a fibric acid medicine for lowering cholesterol
- Cyclosporine
- Danazol

Taking Simvastatin, Vytorin, Zocor, or Simcor with these medication can increase the risk of muscle problems. If you are not sure whether a medicine you take should not be taken with Simvastatin, Vytorin, Zocor, or Simcor, ask your doctor.

What other medications or substances might affect my prescription for Simvastatin, Vytorin, Zocor, or Simcor?

Because of an increased risk of muscle problems, it is important to tell your doctor if you take:

- Fibric acid derivatives (such as fenofibrate)
- Amiodarone (a drug used to treat an irregular heartbeat)
- Verapamil, diltiazem, amlodipine, or ranolazine (drugs used to treat high blood pressure, chest pain associated with heart disease or other heart conditions)
- Large quantities of grapefruit juice (more than 1 quart daily)
- Colchicine (a medicine used to treat gout)
- Voriconazole (an antifungal medicine)
- Large doses of niacin or nicotinic acid

Tell your doctor if you are taking niacin or a niacin-containing product as this may increase your risk of muscle problems, especially if you are Chinese.

It is also important to tell your doctor if you are taking coumarin anticoagulants (drugs that prevent blood clots, such as warfarin).

Why are the prescribing recommendations being changed?

Earlier prescribing recommendations have explained that the risk of muscle problems with Simvastatin, Vytorin, Zocor, or Simcor, including in rare cases muscle breakdown, is greater at higher doses. The prescribing recommendations have been updated over time to reflect new safety information.

The most recent update follows an FDA review of the risk of muscle problems with high-dose Simvastatin, Vytorin, Zocor, or Simcor. That review was based on information reported to the FDA from a clinical study of the highest dose of simvastatin (80mg), as well as on information from other sources.

What are the muscle problems associated with Simvastatin, Vytorin, Zocor, or Simcor?

Simvastatin, Vytorin, Zocor, or Simcor sometimes causes muscle problems, such as muscle pain, tenderness, or weakness. Muscle problems, including muscle breakdown, can be serious in some people and rarely cause kidney damage that can lead to death.

The risk of muscle breakdown with Simvastatin, Vytorin, Zocor, or Simcor is greater when taking higher doses. The risk with the highest doses is greatest during the first year of use. At any dose, the risk of muscle breakdown is also greater in people 65 years of age or older, females, people with kidney or thyroid problems, and with use of certain medications. **Tell your doctor right away if you experience unexplained muscle pain, tenderness, or weakness.**

What other important risk information should I know about Simvastatin, Vytorin, Zocor, or Simcor?

These medications should not be taken by women who are nursing or pregnant or who may become pregnant, by anyone with liver problems, or by people who are allergic to any ingredients of these medications.

Your doctor may do simple blood tests before and during treatment to check for liver problems.

If I have more questions about Simvastatin, Vytorin, Zocor, or Simcor, where should I go for information?

Talk with your doctor. If you have high cholesterol, it is important to stay on a healthy diet and to follow your doctor's instructions on how to manage your high cholesterol.

For more information please visit:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm258384.htm>