

# Information for Patients About June 2011 Changes to the Prescribing Recommendations for Simvastatin and *Vytorin*<sup>®</sup> (ezetimibe/simvastatin)

Simvastatin is available in generic form and under the brand name *Zocor*<sup>®</sup>.  
Simvastatin is also contained in the combination medicine *Vytorin*.

## Who is affected by the June 2011 changes to the prescribing recommendations for simvastatin and *Vytorin*?

Some people taking these medicines are affected and others are not. The June 2011 changes to the prescribing recommendations affect:

- People who take the highest dose of simvastatin (80 mg) or the highest dose of *Vytorin* (10/80 mg). These doses 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 or *Vytorin* at any dose who also take certain other medicines that can increase the risk of muscle problems. See “*What medicines cannot be taken with any dose of simvastatin or Vytorin?*” and “*What other medicines or substances might affect my prescription for simvastatin or Vytorin?*”

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?*”.

## I currently take simvastatin or *Vytorin* and think the June 2011 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 medicines.

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

If your doctor decides that your current dose of simvastatin or *Vytorin* is still right for you, continue to take your medicine as prescribed.

## What medicines cannot be taken with any dose of simvastatin or *Vytorin*?

Do not take simvastatin or *Vytorin* if you also take:

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

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

## What other medicines or substances might affect my prescription for simvastatin or *Vytorin*?

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 were the prescribing recommendations changed in June 2011?

Earlier prescribing recommendations explained that the risk of muscle problems with simvastatin, 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 June 2011 update followed an FDA review of the risk of muscle problems with high-dose simvastatin. That review was based on information that Merck reported to the FDA from a clinical study of the highest dose of simvastatin (80 mg), as well as on information from other sources.

## What are the muscle problems associated with simvastatin?

Simvastatin 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 is greater when taking higher doses, particularly the 80-mg dose of simvastatin or the 10/80-mg dose of *Vytorin*<sup>®</sup> (ezetimibe/simvastatin). The risk with the highest dose 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 the use of certain medicines.

**Tell your doctor right away if you experience unexplained muscle pain, tenderness, or weakness.**

## What other important risk information should I know about simvastatin and Vytorin?

Simvastatin and *Vytorin* 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 medicines.

Your doctor should do simple blood tests to check for liver problems before treatment and if you have symptoms of liver problems during treatment. Tell your doctor right away if you feel tired or weak, or if you have loss of appetite, upper belly pain, dark urine, or yellowing of your skin or the whites of your eyes.

In clinical trials of *Zocor*<sup>®</sup> (simvastatin), side effects included upper respiratory infections, headache, abdominal pain, constipation, and nausea.

In clinical trials of *Vytorin*, side effects included headache, muscle pain, and diarrhea.

This is not a complete list of all risks associated with simvastatin or *Vytorin*.

## What is simvastatin?

Simvastatin is a prescription medicine that is used along with diet to improve cholesterol levels in people with high cholesterol when diet alone is not enough. In patients with heart disease or diabetes, simvastatin, along with a healthy diet, is also used to reduce the risk of heart attack and stroke.

Simvastatin is widely available in generic form and is also available under the brand name *Zocor*. The FDA changed the prescribing recommendations for *Zocor* as well as for generic simvastatin.

## What is Vytorin?

*Vytorin* is a prescription medicine that contains two cholesterol medicines, ezetimibe and simvastatin, in a single tablet. *Vytorin* is used along with diet to improve cholesterol levels in people with high cholesterol when diet alone is not enough. *Vytorin* has not been shown to reduce heart attacks or strokes more than simvastatin alone.

Because *Vytorin* contains simvastatin, the changes to prescribing recommendations for simvastatin regarding the risk of muscle problems also apply to *Vytorin*.

## If I have more questions about simvastatin or Vytorin, 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.

**Please read the Patient Information for Vytorin and discuss it with your doctor. The physician Prescribing Information for Vytorin and the physician Prescribing Information for Zocor also are available.**

This information is also available at [www.simvastatininfocenter.com](http://www.simvastatininfocenter.com).



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