FDA Approves Simcor

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Abbott Laboratories has received U.S. Food and Drug Administration (FDA) approval for Simcor®, the first fixed-dose combination of two widely prescribed cholesterol therapies, Niaspan® (niacin extended-release) and simvastatin (Zocor®). Simcor is approved for use along with diet to lower levels of elevated total cholesterol, LDL, or "bad," cholesterol and triglycerides and to raise HDL, or "good," cholesterol in patients with complex lipid disease do not respond to simvastatin or Niaspan alone.

"Managing cholesterol encompasses many factors, not just lowering LDL. There is a clear need for medicines that both raise good and comprehensively lower the bad components of cholesterol," said Christie Ballantyne, M.D., the Methodist DeBakey Heart and Vascular Center, Houston, and lead Simcor investigator. "Simcor represents an important new option to help patients reach healthy lipid levels."

An estimated 80 million Americans have high levels of the bad LDL cholesterol, and more than 44 million have low levels of the good HDL cholesterol, which the body uses to remove bad cholesterol from the bloodstream. Studies have shown that along with diet, Simcor can help patients with lipid disorders reach their treatment goals by addressing more than just bad cholesterol, targeting multiple lipids with one pill.

"With Simcor, doctors now have a new option for helping patients reach their LDL and HDL cholesterol treatment goals with a combination of two proven therapies," said Eugene Sun, M.D., vice president of Global Clinical Development for Abbott. "Abbott is committed to bringing forward new cholesterol therapies, and Simcor represents a new treatment option for patients in Abbott's rapidly expanding portfolio of cholesterol treatments for lipid disorders."

The American Heart Association, National Cholesterol Education Program (NCEP) and American College of Cardiology recommend more aggressive treatment of HDL to reduce the risk of heart disease. Cholesterol and other lipids can build up in the bloodstream, forming plaque and restricting blood flow, which can lead to heart disease. According to NCEP guidelines, a reduction in LDL of 1 percent is associated with a 1 percent reduction in heart disease risk. Additionally, raising HDL by 1 point is associated with a 2 percent heart disease risk reduction.

Important Safety Information About Simcor

You should not use Simcor if you have liver problems, stomach ulcers or serious bleeding problems or if you allergic to any of Simcor's ingredients. Women who are pregnant, may become pregnant or are breastfeeding should not use Simcor.

Contact your health care provider if you have unexplained muscle pain, tenderness or weakness. These may be signs of a serious but rare muscle disorder from which rare cases of death have occurred.

Flushing (warmth, redness, itching or tingling of the skin) is the most common side effect and may become less frequent over time. Additional symptoms may include rapid heartbeat, shortness of breath, sweating, chills, dizziness, fainting and swelling. Flushing may vary in severity and is more likely to occur when you first start Simcor or when you increase your dose. By taking Simcor at bedtime, flushing will most likely occur during sleep. If the flushing wakes you up, take your time getting up, especially if you feel dizzy or faint or if you take blood pressure medications.

Other common side effects may include headache, itching, nausea, back pain and diarrhea.

Tell your doctor and pharmacist about any other medications, vitamins or dietary supplements you take to avoid possible serious drug interactions.

Do not replace Simcor with the same doses of immediate-release niacin. Liver damage has been reported when substituting sustained-release niacin products with immediate-release niacin at the same doses. Your health care provider may do simple blood tests before and during treatment with Simcor to check for liver problems.

Simcor may cause an increase in blood sugar levels. If you have diabetes, report any changes in blood sugar levels to your health care provider.

Source

Abbott Laboratories press release