August 2010

FDA Approves New SIMCOR 40-mg Strengths

Dear Health Care Provider:

Abbott is pleased to announce the FDA approval of **New SIMCOR 40-mg strengths: 500/40 mg and 1000/40 mg.**

SIMCOR is indicated as an adjunct to diet to reduce total-C, LDL-C, Apo B, non–HDL-C, or TG, or to increase HDL-C in patients with primary hypercholesterolemia and mixed dyslipidemia when treatment with simvastatin monotherapy or niacin extended-release monotherapy is considered inadequate.[1]

Limitations of Use: No incremental benefit of SIMCOR on cardiovascular morbidity and mortality over and above that demonstrated for simvastatin monotherapy and niacin monotherapy has been established.

One Pill Convenience, Now in New 40-mg Strengths: SIMCOR combines simvastatin 40 mg and niacin extended-release in a convenient single tablet

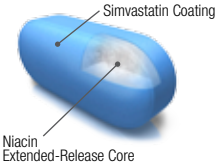
- SIMCOR is also available in 500/20, 750/20, and 1000/20-mg strengths
- SIMCOR is widely available, with Tier 2 coverage on 80% of national managed care plans; co-pay assistance is also available[2]

New SIMCOR 40-mg Strengths

500/40 mg
NDC: 0074-3459-90

1000/40 mg
NDC: 0074-3457-90

Pills are a graphical representation and are not actual size.



Significant HDL-C Efficacy: For simvastatin patients who need increased HDL-C, SIMCOR adds powerful HDL-C improvements

- In SEACOAST II, a double-blind, randomized, multicenter, active-controlled efficacy and safety study, SIMCOR 2000/40 mg increased HDL-C by an additional 24% and lowered LDL-C by an additional 5% after a simvastatin 40-mg run-in[1]*
- In OCEANS, an open-label, randomized, multicenter safety and efficacy study, SIMCOR 2000/40 mg increased HDL-C by an additional 24% and lowered LDL-C by an additional 25% after a simvastatin 40-mg run-in[3]†

Flushing in Clinical Trials: Flushing decreased as treatment continued

- Flushing (warmth, redness, itching, and/or tingling of the skin) occurred in 59% of patients treated with SIMCOR in the SEACOAST study, resulting in 6% of patients discontinuing[1]
- The majority of flushing episodes (85.5%) were mild to moderate[2]

Patient Support Program: Abbott's Heart Alliance® Program provides 24-hour nurse support, every day

- Through Heart Alliance, patients have 24/7 access to a cardiac-experienced nurse and can elect to receive additional ongoing support to help them manage flushing and encourage compliance
- Patients can enroll in Heart Alliance using the 24/7 toll-free number (1.888.4SIMCOR) or on the web at www.simcortablets.com

Safety Information

- SIMCOR is contraindicated in patients with active liver disease or unexplained persistent elevations of serum transaminases, active peptic ulcer disease, arterial bleeding; in women who are pregnant or may become pregnant; and in nursing mothers[1]
- SIMCOR is associated with myopathy, rhabdomyolysis, increases in liver enzymes and glucose levels. Severe hepatic toxicity has occurred when substituting sustained-release niacin for immediate-release niacin at equivalent doses
- Other common adverse events occurring in ≥3% of patients treated with SIMCOR included headache, pruritus, nausea, back pain, and diarrhea

For additional information, please contact your Abbott Sales Representative, or call Abbott Medical Information at 1-800-633-9110.

Sincerely,

Robert J. Padley, M.D.
Project Director, Global Pharmaceutical Research and Development, Abbott

* SEACOAST Study Design: A double-blind, randomized, multicenter, active-controlled, 24-week study compared the efficacy and safety of SIMCOR with low-dose and high-dose simvastatin in adult patients (N=641) with type II hyperlipidemia or mixed dyslipidemia.[2,4] In the high-dose arm (SEACOAST II), patients (n=343) received simvastatin 40 mg daily for ≥2 weeks and then were randomized to receive SIMCOR 1000/40 mg, SIMCOR 2000/40 mg, or simvastatin 80 mg daily. All randomized patients had elevated non–HDL-C levels and LDL-C levels that were either elevated or at goal. The primary efficacy endpoint was percentage change from baseline to Week 24 in non–HDL-C. Secondary efficacy endpoints were percentage change from baseline to Week 24 in other lipids, including LDL-C and HDL-C.

† OCEANS Study Design: An open-label, randomized, multicenter study evaluated the safety and efficacy of SIMCOR in adult patients (N=520) with primary Type II hyperlipidemia or mixed dyslipidemia.[2,3] Patients who continued to have elevated non–HDL-C after receiving simvastatin 40 mg daily for ≥4 weeks were randomized to receive 1 of 2 SIMCOR titration regimens for up to 52 weeks. Doses were titrated over an 8- or 12-week period to a maximum dose of SIMCOR 2000/40 mg daily.

SIMCOR®
niacin EXTENDED-RELEASE/
simvastatin TABLETS

Please see Indications and Important Safety Information on next page.
Please see full Prescribing Information at http://www.rxabbott.com/pdf/simcor_pi.pdf.

Abbott
A Promise for Life

Indications for SIMCOR® (niacin extended-release/simvastatin)[1]

- Lipid-altering agents should be used in addition to a diet restricted in saturated fat and cholesterol when response to diet and other nonpharmacological measures alone has been inadequate.
- SIMCOR is indicated as an adjunct to diet to reduce total-C, LDL-C, Apo B, non-HDL-C, or TG, or to increase HDL-C in patients with primary hypercholesterolemia and mixed dyslipidemia when treatment with simvastatin monotherapy or niacin extended-release monotherapy is considered inadequate.
- SIMCOR is indicated to reduce TG in patients with hypertriglyceridemia when treatment with simvastatin monotherapy or niacin extended-release monotherapy is considered inadequate.
- Limitations of use: No incremental benefit of SIMCOR on cardiovascular morbidity and mortality over and above that demonstrated for simvastatin monotherapy and niacin monotherapy has been established.

Important Safety Information for SIMCOR

- SIMCOR is contraindicated in patients with active liver disease or unexplained persistent elevations of serum transaminases, active peptic ulcer disease, arterial bleeding; in women who are pregnant or may become pregnant; in nursing mothers; and in patients with hypersensitivity to any product ingredient.
- SIMCOR contains simvastatin, which occasionally causes myopathy manifested as muscle pain, tenderness, or weakness with CK levels above 10X ULN. Myopathy sometimes takes the form of rhabdomyolysis with or without acute renal failure secondary to myoglobinuria, and rare fatalities have occurred. Risks of myopathy increase with higher doses, advanced age (≥65), hypothyroidism, renal impairment, and concomitant use of cyclosporine, danazol, gemfibrozil, amiodarone, verapamil, and potent CYP3A4 inhibitors.
- Myopathy and/or rhabdomyolysis have been reported when simvastatin is used in combination with lipid-altering doses (≥1 g/day) of niacin. Advise patients to promptly report unexplained muscle pain, tenderness, or weakness. Discontinue SIMCOR if myopathy is diagnosed or suspected.
- SIMCOR should not be substituted for equivalent doses of immediate-release niacin. Severe hepatic toxicity has occurred in patients substituting sustained-release niacin for immediate-release niacin at equivalent doses. If switching from niacin preparations other than niacin extended-release, initiate with the lowest SIMCOR dose. Doses greater than 2000/40 mg are not recommended.
- SIMCOR should be used with caution in patients with renal disease, a past history of liver disease, and/or consume substantial quantities of alcohol.
- SIMCOR can increase serum transaminases. Monitor liver enzymes before and during treatment and discontinue therapy if enzyme levels >3X ULN persist, or if levels are associated with symptoms of nausea, fever, and/or malaise.
- SIMCOR can increase serum glucose levels. Glucose levels should be monitored in diabetic or potentially diabetic patients, particularly during the first few months of use.
- SIMCOR can reduce platelet count and phosphorus levels, and increase uric acid levels and prothrombin time (PT). In patients taking coumarin anticoagulants, monitor PT and INR before and during treatment.
- The most common adverse event with SIMCOR is flushing (warmth, redness, itching and/or tingling of the skin). Flushing may vary in severity and is more likely to occur with initiation of therapy or during dose increases.
- Other common adverse events reported by ≥3% of patients receiving SIMCOR were headache, pruritus, nausea, back pain, and diarrhea.

References: 1. SIMCOR [package insert.] North Chicago, IL: Abbott Laboratories. **2.** Data on file, Abbott Laboratories. **3.** Karas RH, Kashyap ML, Knopp RH, et al. Long-term safety and efficacy of a combination of niacin extended release and simvastatin in patients with dyslipidemia: the Oceans Study. *Am J Cardiovasc Drugs.* 2008;8(2):69-81. **4.** Ballantyne CM, Davidson MH, McKenney JM, et al. Comparison of the efficacy and safety of a combination tablet of niacin extended-release and simvastatin with simvastatin 80 mg monotherapy: the SEACOAST II (high-dose) study. *J Clin Lipid.* 2008;2:79-90.

SIMCOR®
niacin EXTENDED-RELEASE/
simvastatin TABLETS

Please see full Prescribing Information at http://www.rxabbott.com/pdf/simcor_pi.pdf.

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