
WHAT CAN YOU DO FOR YOUR SIMVASTATIN PATIENTS TO
DRIVE HDL-C HIGHER?
SIMCOR is used with diet to reduce elevated LDL-C and increase HDL-C in patients with primary hypercholesterolemia and mixed dyslipidemia when simvastatin 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.
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.
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.
Please see Indications/Important Safety Information on inside panel.
Please see accompanying Full Prescribing Information.
SIMCOR®
niacin EXTENDED-RELEASE/
simvastatin TABLETS
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A Promise for Life

For your simvastatin patients

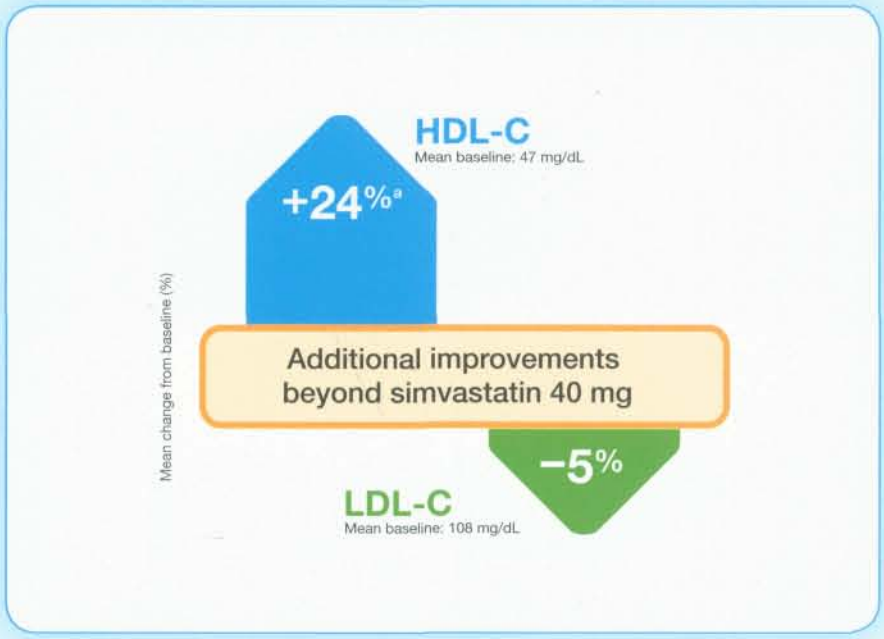
DELIVER POWERFUL HDL-C IMPROVEMENTS

SIMCOR provides significant HDL-C improvements over simvastatin

SEACOAST II (high-dose) study design.[1-3] A double-blind, randomized, multicenter, active-controlled, 24-week study (n=343) compared the efficacy and safety of SIMCOR 1000/40 mg and 2000/40 mg with simvastatin 80 mg in adult patients with Type II hyperlipidemia or mixed dyslipidemia. Patients received simvastatin 40-mg/day run-in 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, HDL-C, and TG.

SEACOAST II: Additional SIMCOR 2000/40 mg efficacy at 24 weeks after a run-in with simvastatin 40 mg (n=98)

Primary endpoint: non–HDL-C (–8% from 144 mg/dL mean baseline)



Additional efficacy data at 24 weeks following simvastatin 40 mg run-in

- **SIMCOR 2000/40 mg (n=98): TG, –32%[b].**
- **SIMCOR 1000/40 mg (n=111): HDL-C, 15%[a]; LDL-C, –7%; TG, –23%[b]; non–HDL-C, –7%.**
- **Simvastatin 80 mg (n=113): HDL-C, 0.1%; LDL-C, –11%; TG, 0.3%[b]; non–HDL-C, –6%.**

Mean baseline values are shown in graph, except non–HDL-C was 141 mg/dL for the SIMCOR 1000/40-mg arm and 135 mg/dL for the simvastatin 80-mg arm.

[a]Significant vs simvastatin 80 mg, $P<0.05$.
[b]Medians are reported for TG.

The independent effect of raising HDL-C on the risk of coronary and cardiovascular morbidity and mortality has not been determined[1]

Indication

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.

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.

Safety Information

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. Risk of myopathy increases with higher doses, advanced age (≥65), hypothyroidism, renal impairment, and concomitant use of cyclosporine, danazol, gemfibrozil, amiodarone, verapamil, and potent CYP3A4 inhibitors.

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A RANGE OF DOSING STRENGTHS TO EXPAND YOUR TREATMENT OPTIONS

SIMCOR is available in 5 dosage strengths to provide flexible dosing and titration[1]

*Patients previously receiving niacin products other than niacin extended-release tablets should be started on SIMCOR at the lowest recommended starting dose. The initial dose for patients already receiving niacin extended-release should not exceed 2000/40 mg once daily.

†The dose of niacin extended-release should not be increased by more than 500 mg daily every 4 weeks.

- Recommended maintenance dose: 1000/20 mg to 2000/40 mg once daily[1]
- Doses greater than 2000/40 mg daily are not recommended
- **According to the AHA**, *dietary supplement niacin must not be used as a substitute for prescription niacin*[4]

ONE product, ONE co-pay, and widely covered

- SIMCOR is a combination product priced comparably to NIASPAN® (niacin extended-release) alone[2]
- SIMCOR is Tier 2 for 81% of patients covered by national managed care plans

Safety Information

Myopathy and rhabdomyolysis

Myopathy and/or rhabdomyolysis have been reported when simvastatin is used in combination with lipid-altering doses (≥1 g/day) of niacin. Myopathy sometimes takes the form of rhabdomyolysis with or without acute renal failure secondary to myoglobinuria, and rare fatalities have occurred. The risk of myopathy/rhabdomyolysis is dose-related and is increased by high plasma concentrations of a statin.

Liver function

Severe hepatic toxicity has occurred in patients substituting sustained-release niacin products for immediate-release niacin at equivalent doses. If switching from niacin preparations other than niacin extended-release, initiate with lowest SIMCOR dose; niacin extended-release can be converted at equivalent doses. 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.

In patients with diabetes

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.

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SIMCOR®
niacin EXTENDED-RELEASE/
simvastatin TABLETS

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.** 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 Lipidol.* 2008;2:79-90. **4.** American Heart Association. Primary prevention in the adult: AHA recommendation. Available at: http://www.americanheart.org/presenter.jhtml?identifier=4704. Accessed January 25, 2011.

SIMCOR®
niacin EXTENDED-RELEASE/
simvastatin TABLETS

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HELP YOUR PATIENTS UNDERSTAND FLUSHING WITH THESE POINTS

Most patients will experience flushing

- In the SEACOAST trial (n=403), 59% of patients experienced flushing to some degree; 6% discontinued therapy as a result[1]*
- Other common adverse events reported by ≥3% of patients receiving SIMCOR were headache, pruritus, nausea, back pain, and diarrhea[1]

Patients were permitted to take 325 mg of aspirin 30 minutes prior to study drug to help manage flushing[1]

Patients may not recognize common symptoms of flushing

- Flushing is different for everyone, and may be experienced as warmth, redness, itching, and/or tingling of the skin
- Flushing is most likely to occur on the face and upper body
- Patients should be advised of the symptoms of flushing and how they differ from the symptoms of an MI

Patients may not understand what causes flushing

- Flushing occurs when the body responds to niacin through the dilation of the capillaries, increasing the flow of blood to the surface of the skin

Patients may not know flushing can subside over time with consistent SIMCOR use[1]

Tips for taking SIMCOR

Take aspirin (up to the recommended dose of 325 mg) 30 minutes before taking SIMCOR to help reduce the frequency and severity of flushing.

Take SIMCOR at bedtime so flushing will most likely occur during sleep.

Avoid alcohol, hot beverages, and spicy foods near the time of taking SIMCOR to help reduce the symptoms of flushing.

Take SIMCOR with a low-fat snack to help manage upset stomach.

If awakened by flushing at night, the patient should get up slowly, especially if feeling dizzy, faint, or taking blood pressure medicines.

Additional patient counseling is available 24/7 through Heart Alliance nurses

- 24/7 nurse support, educational mailings, and patient starter kits available by phone at 1-888-4SIMCOR (1-888-474-6267) or visit www.simcortablets.com

Heart Alliance®
Success from the start.

*In the SEACOAST study, the incidence of flushing (percentage of patients reporting at least 1 flushing event) and flushing intensity (mild, moderate, severe) were measured by flushing logs.[2]

In simvastatin patients

DRIVE HDL-C HIGHER

- **Powerful HDL-C improvements[1-3]**
- **A combination of two proven agents, each supported by compelling evidence**
- **24/7 nurse counseling and support is available through Heart Alliance®**
- **ONE product, ONE co-pay, and widely covered**

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Indication

SIMCOR is used with diet to reduce elevated LDL-C and increase HDL-C in patients with primary hypercholesterolemia and mixed dyslipidemia when simvastatin 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.

Safety Information

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.

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