

PHARMACY PRODUCT ALERT



Pharmacist Counseling Tips for SIMCOR[®]
(niacin extended-release/simvastatin tablets)

Talking to Your Patients About Flushing

Abbott
A Promise for Life

Counseling Tips that May Enhance Patient Understanding of SIMCOR

Emphasize why you feel that taking SIMCOR is so important to cholesterol management

SIMCOR combines NIASPAN (niacin extended-release) and simvastatin to provide powerful dual-lipid management¹

Explain that flushing is a common side effect of SIMCOR

Flushing may vary in severity and is more likely to occur with initiation of therapy or during dose increases

Describe what flushing might feel like

Redness, warmth, itching, and/or a tingling of the skin

Discuss simple steps patients can take to help manage flushing

Urge patients to make these a part of their daily SIMCOR regimen

Reassure patients that flushing may decrease with continued SIMCOR use

Flushing may subside after several weeks of consistent use with SIMCOR

Simple tips to help manage flushing and minimize GI upset



Take aspirin or a nonsteroidal anti-inflammatory drug (eg, ibuprofen) approximately 30 minutes prior to the SIMCOR dose, with a doctor's approval



Take SIMCOR at bedtime



Avoid hot or alcoholic beverages and spicy food near the time of taking SIMCOR



Take SIMCOR with a low-fat snack

The most common adverse event with SIMCOR is flushing (warmth, redness, itching and/or tingling) which occurred in 59% of patients and resulted in study discontinuation for 6% of patients. Flushing may vary in severity and is more likely to occur with initiation of therapy or during dose increases. Spontaneous reports with niacin extended-release and clinical studies of SIMCOR suggest that flushing may be accompanied by symptoms of dizziness, syncope, tachycardia, palpitations, shortness of breath, sweating, chills and/or edema.

**Please see Indications/Important Safety Information at the end of this email.
Please see link below for full Prescribing Information.**

The Heart Alliance[®] Program Demonstrates Our Commitment to Patient Care



Provides patients with educational materials and money saving offers. The Heart Alliance program supports your counseling on flushing. Visit www.simcortablets.com for more information and patient enrollment.



Indications and Important Safety Information

Indications¹

- SIMCOR (niacin extended-release/simvastatin) 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 (Fredrickson type IIa and IIb) when treatment with simvastatin monotherapy or niacin extended-release monotherapy is considered inadequate.
- SIMCOR is indicated to reduce TG in patients with hypertriglyceridemia (Fredrickson type IV hyperlipidemia) when treatment with simvastatin monotherapy or niacin extended-release monotherapy is considered inadequate.
- 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.
- 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

- 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, 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. The risk of myopathy/rhabdomyolysis is dose-related and is increased by high plasma concentrations of a statin.
- The use of SIMCOR concomitantly with potent CYP3A4 inhibitors: itraconazole, ketoconazole and other antifungal azoles, erythromycin, clarithromycin and telithromycin, HIV protease inhibitors, nefazodone, and grapefruit juice in large quantities (>1 quart daily) should be avoided because of the increased risk of myopathy/rhabdomyolysis. Concomitant use of SIMCOR with cyclosporine, danazol, gemfibrozil, other fibrates, amiodarone, and verapamil should also be avoided because of increased risk of myopathy/rhabdomyolysis.
- Myopathy and/or rhabdomyolysis have been reported when simvastatin is used in combination with lipid-altering doses (≥ 1 g/day) of niacin. Patients on SIMCOR should be monitored for muscle pain, tenderness or weakness, particularly during the initial month of treatment or during upward dose titration. Periodic CK determinations may be considered in such situations. SIMCOR therapy should be discontinued if CK levels above 10x ULN occur or 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 immediate-release niacin to SIMCOR, initiate with the lowest SIMCOR dose (500/20 mg) and titrate to the desired therapeutic response. Doses greater than 2000/40 mg are not recommended.
- SIMCOR should be used with caution in patients who consume substantial quantities of alcohol and/or who have a past history of liver disease.
- Liver function tests should be performed on all patients before treatment begins and every 12 weeks for the first 6 months, and periodically thereafter (eg, at approximately 6-month intervals). Should an increase in transaminase levels of more than 3x ULN persist, or if transaminase elevations are associated with symptoms of nausea, fever, and/or malaise, withdrawal of SIMCOR therapy is recommended.
- Niacin treatment can increase fasting blood glucose. Glucose levels should be closely monitored in diabetic or potentially diabetic patients particularly during the first few months of use. Adjustment of diet and/or hypoglycemic therapy or discontinuation of SIMCOR may be necessary.
- In patients taking coumarin anticoagulants, monitor prothrombin time and INR before initiating SIMCOR and frequently after initiation or alteration of SIMCOR therapy until stable.
- Caution should be exercised when SIMCOR is administered to patients with renal disease.
- The most common adverse event with SIMCOR is flushing (warmth, redness, itching and/or tingling) which occurred in 59% of patients and resulted in study discontinuation for 6% of patients. Flushing may vary in severity and is more likely to occur with initiation of therapy or during dose increases. Spontaneous reports with niacin extended-release and clinical studies of SIMCOR suggest that flushing may be accompanied by symptoms of dizziness, syncope, tachycardia, palpitations, shortness of breath, sweating, chills and/or edema.
- Other common adverse events occurring in $\geq 3\%$ of patients treated with SIMCOR included headache, pruritus, nausea, back pain, and diarrhea.

Full Prescribing Information is available at
http://rxabbott.com/pdf/simcor_pi.pdf

References: 1. SIMCOR [package insert]. North Chicago, IL: Abbott Laboratories.

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