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PHARMACY PRODUCT ALERT

RX INSIDER

Helpful information for counseling patients

Patients who take SIMCOR may experience a side effect called flushing.[1] Flushing is a common side effect of niacin-based therapy that may subside after several weeks of consistent SIMCOR use. More than half of the patients in clinical trials of SIMCOR experienced flushing. Flushing is a warmth, redness, itching and/or tingling sensation of the face, neck, chest, and/or back. For some, flushing may be accompanied by rapid or pronounced heartbeat, shortness of breath, sweating, chills, dizziness, fainting, and/or swelling. Flushing may vary in severity and is more likely to occur when starting therapy or during dose increases.

Tips to help manage flushing...

- **30 minutes prior to the SIMCOR dose, take an aspirin** or nonsteroidal anti-inflammatory drug, such as ibuprofen, with your doctor's approval
- **Avoid drinking hot or alcoholic beverages or also eating spicy food** around the time of taking SIMCOR
- Take SIMCOR **at bedtime**

Patient support program available

The Heart Alliance® program provides ongoing support for patients. Patients enrolled receive:

- Personalized nurse follow up when initiating therapy
- Access to a medical information specialist available 24 hours a day, 7 days a week at 1-888-4-SIMCOR
- Educational materials on cholesterol, healthy lifestyles and medication information

Patients can receive a **FREE 30-day trial of SIMCOR** and sign up for the Heart Alliance program by visiting **www.simcortablets.com**

SIMCOR® niacin EXTENDED-RELEASE/ simvastatin TABLETS

*The initial dose for patients already receiving niacin extended-release should not exceed 2000/40 mg daily.

Please visit **www.simcortablets.com** for full Prescribing Information.

Indications and Important Safety Information

Indications [1]

- 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 ≥3% of patients treated with SIMCOR included headache, pruritus, nausea, back pain, and diarrhea.

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

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