

This update is informational and intended for prescribers, pharmacists and nurses



SIMVASTATIN RISK UPDATE

The Food and Drug Administration (FDA) has recently reviewed clinical data from a study of simvastatin and last month issued **new warnings** about the increased risk of myopathy or muscle injury in those receiving 80mg doses compared to lower doses. This has prompted the FDA to educate patients and Healthcare Professionals regarding these risks and the **risks of combining certain medications with simvastatin**.

WHAT IS IMPORTANT TO KNOW?

CONSIDER LOWER DOSES OF SIMVASTATIN OR ANOTHER AGENT IF LDL LOWERING IS NOT ACHIEVED WITH THE 40MG DOSE.

DRUG INTERACTIONS

NEW RECOMMENDATIONS ASSOCIATED WITH SIMVASTATIN

Simvastatin should not be used with:

- Itraconazole
- Ketoconazole
- Erythromycin
- Clarithromycin
- Telithromycin
- Protease Inhibitors
- Nefazodone

Do not use more than 10mg of simvastatin with:

- Gemfibrozil
- Cyclosporine
- Danazol

Do not use more than 20mg of simvastatin with:

- Amiodarone
- Verapamil

Do not use more than 40mg of simvastatin with

- Diltiazem

BE AWARE THAT THE FDA HAS STRENGTHENED CERTAIN WARNINGS SURROUNDING DRUG INTERACTIONS WITH SIMVASTATIN. YOU MAY RECEIVE PHONE CALLS OR SEE REJECTIONS AT THE PHARMACY IF THESE MEDICATIONS ARE GIVEN TOGETHER.

EDUCATE PATIENTS ON THE SYMPTOMS OF MYOPATHY AND RHABDOMYOLYSIS AND WHEN TO CONTACT THEIR HEALTH CARE PROVIDER.

MYOPATHY

Myopathy is a known side effect for **all** statins. The risk of developing this increases as the dosage increases. Potential elevations in creatine kinase blood levels may occur.

Symptoms include :

- Muscle pain
- Tenderness
- Weakness

RHABDOMYOLYSIS

Rhabdomyolysis is a serious form of myopathy where muscle fibers break down and release the protein myoglobin, which can damage the kidneys and potentially result in renal failure.

Risk factors include:

- Age > 65 years
- Hypothyroidism
- Poor kidney function

Symptoms include:

- Myalgias or muscle pain especially in the thighs, calves or lower back
- Tenderness
- Malaise
- Fever
- Dark urine
- Nausea or vomiting

Simvastatin is available as a generic single ingredient product or in combination with ezetimibe (Vytorin®) or Niacin (Simcor®)