Simvastatin

Increased risk of muscle injury with high doses

USA. The US FDA warned health-care professionals and patients that there is an increased risk of myopathy in patients taking the highest approved 80mg dose of simvastatin (cholesterol-lowering medicine) , compared to patients taking lower doses of simvastatin and possible other statin medications. The most serious form of myopathy is rhabdomyolysis.

Rhabdomyolysis is a rare adverse event reported with all statins. The risk of myopathy is also increased when simvastatin , especially at the higher doses, is used with certain drugs. The Agency recommends dose limitations of simvastatin as follows, due to the potential drug-drug interactions.

Do not use simvastatin with these medications:

- Itraconazole
- Ketoconazole
- Erythromycin
- Clarithromycin
- Telithromycin
- HIV protease inhibitors
- Nefazodone

Do not use more than 10mg of simvastatin with these medications:

- Gemfibrozil
- Cyclosporine
- Danazol

Do not use more than 20mg of simvastatin with these medications:

- Amiodarone
- Verapamil

Do not use more than 40mg of simvastatin with this medication:

- Diltiazem

Myopathy and rhabdomyolysis are listed as possible side effects in the simvastatin and other statin drug labels. Known risk factors for developing rhabdomyolysis include age (> 65 years), low thyroid hormone levels (hypothyroidism) and poor kidney function.

The above notification has come from the US FDA's review of data from the clinical trial called the Study of the Effectiveness of Additional Reductions in Cholestrol and Homocysteine (SEARCH) trial, and other sources. The SEARCH trial evaluated over 6.7 years the number of major cardiovascular events (heart attack, revascularization and cardiovascular death) in 6031 patients taking 80 mg of simvastatin compared to 6033 patients taking 20 mg of simvastatin. All patients in the study had previously had a heart attack. According to the Agency, preliminary results showed that more patients in the simvastatin 80 mg group developed myopathy compared to patients in the simvastatin 20 mg group (52 [0.9%] cases compared to 1 case [0.02%]). Moreover, 11 (0.02%) of the patients in the simvastatin 80 mg group developed rhabdomyolysis compared to no patients in the simvastatin 20 mg group.

(See WHO Pharmaceuticals Newsletter No. 4, 2008 for increased risk of rhabdomyolysis with combination of simvastatin and amiodarone in the USA).

Reference:

1. WHO Pharmaceuticals Newsletter No. 2, 2010 Page 10
2. Safety, US FDA 19 March 2010 (www.fda.gov)

Any such reports in your practice? Have you noted the same or similar Adverse Drug Reactions? If yes, please report to:

The Pharmacovigilance Department, Pharmacy and Poisons Board.

You are receiving this message as a service that you have subscribed to the Pharmacovigilance e-shot

Department of Pharmacovigilance
Pharmacy and Poisons Board
Lenana Road
Ministry of Medical Services
P.O. Box: 27663-00506
Nairobi, KENYA
pv@pharmacyboardkenya.org
www.pharmacyboardkenya.org
(+254-20-) 3562107
(+254-0-) 733884411 / 720608811
(+254-20-) 2713431 / 2713409

Remember…

"You need not be certain…

Just be suspicious"

Report all suspected cases of ADRs and Poor Quality Medicines