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Inland Empire Health Plan

PHARMACY TIMES

BY IEHP PHARMACEUTICAL SERVICES DEPARTMENT

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This letter provides important new safety information regarding simvastatin containing medicines (brand name products include Zocor, Vytorin, and Simcor).

---Important Safety Information---

On 6/8/2011, the FDA released a new safety announcement related to the prescribing and use of cholesterol lowering medication simvastatin. Through post marketing research and surveillance, the FDA has found an elevated risk of myopathy (muscle injury) particularly during the first 12 months of use. The FDA is recommending that simvastatin 80 mg be used only in patients who have been taking this dose for 12 months or more and have not experienced any muscle toxicity. Simvastatin 80 mg should not be prescribed to new patients. The FDA has revised the drug labels for simvastatin and Vytorin to include the new simvastatin 80 mg dosing restrictions. The labels for simvastatin, Vytorin and Simcor are updated to include new dosing recommendations for drug interactions with simvastatin. More information related to safety announcement can be found at: <http://www.fda.gov/Drugs/DrugSafety/ucm256581.htm>.

Due to potential for drug interactions, concomitant use of the following medications with any available dose of simvastatin is now contraindicated (see table below):

| Interactive Drug | Previous PI Labeling | Updated PI Labeling |
|---|--------------------------------------|---------------------|
| Strong CYP3A4 inhibitors (eg, itraconazole, ketoconazole, posaconazole, HIV protease inhibitors, erythromycin, clarithromycin, telithromycin, nefazodone) | Avoid | Contraindicated |
| Gemfibrozil, cyclosporine, danazol | Do not exceed 10mg simvastatin daily | Contraindicated |

Other medications now have warning for potential drug interactions (see table below):

| Interactive Drug | Previous PI Labeling | Updated PI Labeling |
|------------------------|--------------------------------------|---|
| Amiodarone, Verapamil | Do not exceed 20mg simvastatin daily | Do not exceed <u>10mg</u> simvastatin daily |
| Diltiazem | Do not exceed 40mg simvastatin daily | Do not exceed <u>10mg</u> simvastatin daily |
| Amlodipine, Ranolazine | No dose restrictions | Do not exceed <u>20mg</u> simvastatin daily |

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---IEHP Formulary---

| Low to Medium Potency In Lowering LDLs & Total Cholesterol | High Potency In Lowering LDLs & Total Cholesterol | Combination/Other Products |
|---|--|--|
| Zocor (simvastatin) - F Pravachol (pravastatin) - F Mevacor (lovastatin) - F Lescol (fluvastatin) – NF | Crestor (rosuvastatin) - NF Lipitor (atorvastatin) – NF Livalo (pitavastatin) - NF | Simcor (simvastatin/niacin) - NF Vytorin (simvastatin/ezetimibe) - NF <i>Other:</i> Zetia (ezetimibe) – NF [Part D] Niaspan (niacin) – F |

F – Formulary, NF – Non-formulary

If you have any questions or comments regarding this change, please call IEHP Pharmaceutical Services Department at 909-890-2067.