FDA adds diabetes, memory loss warnings to statins

On February 28, 2012, the FDA announced that warnings will be added to the labels of statins to indicate that statins may cause hyperglycemia, which may lead to a diagnosis of type II diabetes mellitus, and could cause memory loss. Statins are oral medications that are used to reduce elevations in total cholesterol and to raise HDL-levels. Statins are of great benefit to many patients, and the FDA states that this new information should not scare people into not taking the medications. FDA states that reports of certain cognitive effects such as memory loss and confusion in patients who are taking statins are usually reversed by stopping the use of the statin. FDA also reports that patients taking statins will no longer need routine periodic monitoring of liver enzymes since serious liver injury with statins is rare and unpredictable and monitoring liver enzymes does not appear to be effective in detecting or preventing this rare side effect.

Statins lower total cholesterol through inhibition of HMG-CoA Reductase. This inhibition reduces the quantity of mevalonic acid, a precursor of cholesterol. The reduction of cholesterol that is synthesized de novo leads to an increase in cholesterol uptake, thus enhancing the clearance of LDL. The mechanism through which these drugs cause hyperglycemia and cognitive abnormalities is unclear. Patients with hyperglycemia may present with frequent urination, increased thirst, blurred vision, fatigue, and headache. These are all early symptoms that usually do not become apparent until blood glucose levels are greater than 200 mg/dL. Hyperglycemia is confirmed by fasting blood glucose levels and glycated hemoglobin A1c. Type II diabetes is diagnosed when a patient’s fasting blood glucose level is >126 mg/dL on two separate readings, when a patient’s HbA1c ≥ 6.5%, or when a patient’s glucose level is >200 mg/dL 2 hours after an oral glucose tolerance test. There appears to be a small increased risk of developing diabetes in patients who are taking statins (~10%). Patients with cognitive abnormalities may present with memory loss, confusion, and abnormal behaviors. Cognitive abnormalities associated with the use of statins are rare and can be reversed by stopping the offending agent.

References:

- Simvastatin. Lexi-Comp (Lexi-Drugs) [computer program]. Lexi-Comp, Inc; February 29, 2012.

Prepared By: Lyndee Bilpuh, Doctor of Pharmacy Candidate