PATIENT SAFETY BLOG

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New Safety Concerns Over Celexa, Proton Pump Inhibitors

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A few widely used drugs once again are coming under heated fire, one thanks to the FDA and the other class courtesy of a consumer watchdog organization.

High doses of Celexa, an antidepressant, can cause abnormal heart rhythms, prompting the feds to issue a new warning that it should not be prescribed at doses higher than 40 mg per day. Disrupting the heart's regular electrical activity can be serious and potentially fatal. Celexa packaging will now include a safety warning.

Available as a brand-name or generic drug, Celexa belongs to the class of antidepressants called selective serotonin reuptake inhibitors (SSRIs), which have been shown to be effective in treating major depression. Doses greater than 40 mg, the FDA says, are not of greater benefit. Sometimes Celexa is prescribed for other psychological disorders, a practice known as "off-label" treatment, so there is no "proper" dosage for such uses.

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Patients with low potassium and magnesium are at increased risk of the serious heart problems from Celexa, says the FDA. Talk to your doctor if you have been prescribed a daily dose of more than 40mg. If you have experienced irregular heartbeat, shortness of breath, dizziness or fainting while taking this drug, contact your doctor immediately.

Public Citizen has raised the flag of concern about a class of drugs called proton pump inhibitors (PPIs). The organization wants the FDA to require a "black box" warning on labels for Nexium, Prilosec, Prevacid, Protonix and similar drugs prescribed for acid reflux.

The “black box” is the FDA’s strongest label warning, and is so named because it’s featured prominently and encircled by a black box.

Public Citizen says proton pump inhibitors, which are also widely prescribed for off-label uses, pose a risk of long-term dependence and other dangerous side effects such as an increased risk of bone fractures, infections, diarrhea and magnesium deficiency leading to heart problems.

In May 2010, the FDA did issue a warning about the risk of bone fractures from heartburn drugs, and updated it in March 2011, indicating that the risk appears to be linked to high doses of the medications used over a long period of time.

According to Public Citizen, acid reflux drugs were prescribed more than 119 million times in 2009 and generated sales in the United States of $13.6 billion. One in 20 people in the developed world take a PPI to reduce the production of stomach acid. If you’re one, now is the time to review your use with your doctor.

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