FDA adds more warnings to antidepressant's label

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Celexa dosing should not exceed 40 mg a day, agency says.

(HealthDay) -- In a follow-up to a warning that high doses of the popular antidepressant Celexa can cause potentially fatal abnormal heart rhythms, the U.S. Food and Drug Administration has issued new dosing and use recommendations.

Last August, the FDA said doses of Celexa (citalopram hydrobromide) greater than 40 milligrams a day can cause changes in the electrical activity of the heart, which can lead to abnormal heart rhythms, including a potentially deadly arrhythmia known as Torsade de Pointes.

Patients at high risk include those with preexisting heart conditions (including congestive heart failure) and those prone to low levels of potassium and magnesium in the blood, the FDA said.

At the time, the drug label was revised to include the new dosage limit as well as information about the potential for abnormal heart electrical

activity and rhythms.

The latest recommendations note that Celexa in any dose should not be given to patients with certain conditions due to the risk of suffering these heart problems. However, it may be important for some patients to take Celexa, so the label has been changed to describe the particular cautions required when giving the drug to these patients.

Here are the latest FDA recommendations:

- Celexa should not be used at doses greater than 40 milligrams (mg).
- Celexa is not recommended for use in patients with congenital long QT syndrome, bradycardia, hypokalemia, hypomagnesemia, recent heart attack, or uncompensated heart failure.
- Use of the Celexa is also not recommended in patients who are taking other drugs that prolong the QT interval.
- The maximum recommended dose of Celexa is 20 mg per day for patients with liver impairment, patients who are older than 60, patients who are CYP 2C19 poor metabolizers, or patients who are also taking cimetidine (Tagamet) or another CYP 2C19 inhibitor. All of these factors lead to increased blood levels of Celexa, increasing the risk of QT interval prolongation and Torsade de Pointes, the FDA said.

Celexa belongs to a class of antidepressants called selective serotonin reuptake inhibitors (SSRIs), which also include widely used medications such as Paxil, Prozac and Zoloft.

More information: The American Academy of Family Physicians has more about antidepressants.