Celexa (citalopram hydrobromide) - Drug Safety Communication: Revised Recommendations, Potential Risk of Abnormal Heart Rhythms

U.S. Food & Drug Administration

AUDIENCE: Psychiatry, Cardiology

ISSUE: FDA is clarifying dosing and warning recommendations for the antidepressant Celexa (citalopram hydrobromide; also available in generic form). In August 2011, FDA issued a Drug Safety Communication (DSC) stating that citalopram should no longer be used at doses greater than 40 mg per day because it could cause potentially dangerous abnormalities in the electrical activity of the heart. Citalopram use at any dose is discouraged in patients with certain conditions because of the risk of QT prolongation, but because it may be important for some of those patients to use citalopram, the drug label has been changed to describe the particular caution that needs to be taken when citalopram is used in such patients. The revised drug label also describes lower doses that should be used in patients over 60 years of age.

Read the FDA Drug Safety Communication for additional information.

BACKGROUND: Celexa (citalopram hydrobromide; also available in generic form) is in a class of antidepressants called selective serotonin reuptake inhibitors (SSRIs).

RECOMMENDATIONS:

- Citalopram is not recommended for use at doses greater than 40 mg per day because such doses cause too large an effect on the QT interval and confer no additional benefit.
- Citalopram is not recommended for use in patients with congenital long QT syndrome, bradycardia, hypokalemia, or hypomagnesemia, recent acute myocardial infarction, or uncompensated heart failure.
- Citalopram use is also not recommended in patients who are taking other drugs that prolong the QT interval.
- The maximum recommended dose of citalopram is 20 mg per day for patients with hepatic impairment, patients who are older than 60 years of age, patients who are CYP 2C19 poor metabolizers, or patients who are taking concomitant cimetidine (Tagamet) or another CYP2C19 inhibitor, because these factors lead to increased blood levels of citalopram, increasing the risk of QT interval prolongation and Torsade de Pointes.

See the FDA Drug Safety Communication for additional recommendations for

healthcare professionals and patients.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm [1]
- Download form [2] or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

[03/28/2012 - Drug Safety Communication [3] - FDA]

Previous MedWatch Alert:

[08/24/2011 [4]]

SOURCE [5]

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Links:
[1] http://www.fda.gov/MedWatch/report.htm
[2] http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm
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