

SPINE SAFETY WARNING:

Information for Healthcare Professionals: Celexa (citalopram hydrobromide) Tablets and Oral Solution: Labeling Changes

According to MedWatch, FDA notified healthcare professionals of labeling changes for Celexa (citalopram hydrobromide) Tablets and Oral Solution. The following has been added to the labeling:

CONTRAINDICATIONS

- Celexa is contraindicated in patients with congenital long QT syndrome (see WARNINGS, PRECAUTIONS, and Drug Interactions).

WARNINGS

QT-Prolongation and Torsade de Pointes

- Citalopram causes dose-dependent QT prolongation and should not be dosed above 40 mg/day. Torsade de Pointes has been reported postmarketing. Celexa should not be used in patients with congenital long QT syndrome. Hypokalemia and hypomagnesemia should be corrected prior to initiation of treatment.

PRECAUTIONS

QT-Prolongation and Torsade de Pointes

- Citalopram causes dose dependent QT prolongation and should not be dosed above 40 mg/day. Torsade de Pointes has been reported postmarketing. Celexa should not be used in patients with congenital long QT syndrome. Hypokalemia and hypomagnesemia should be corrected prior to initiation of treatment and periodically monitored. ECG monitoring is recommended in patients with congestive heart failure, bradyarrhythmias, or patients on concomitant medications that prolong the QT interval. Dose escalations over 20 mg/day in CYP2C19 poor metabolizers or patients taking concomitant cimetidine or another CYP2C19 inhibitor are not recommended.

Drug Interactions

Drugs that Prolong the QT interval

- ECG monitoring is recommended with concomitant medications that have demonstrated prolongation of the QT interval (see WARNINGS- QT-Prolongation and Torsade de Pointes)

ADVERSE REACTIONS

ECG Changes

- In a thorough QT study, Celexa was found to be associated with a dose-dependent increase in the QTc interval (see WARNINGS - QT-Prolongation and Torsade de Pointes).

The North American Spine Society is committed to quality patient care through promotion of patient safety and prevention of medical errors. NASS monitors a variety of government and other resources for patient safety related notices that may be useful to our members. Information from these notices is also archived on the NASS website at <http://www.spine.org/Pages/PracticePolicy/ClinicalCare/SpineSafetyAlerts/Default.aspx>. This information is provided as a service for information and education only.