FDA Alert for Healthcare Professionals
Atomoxetine (marketed as Strattera)

FDA Alert [09/05]: Suicidal Thinking in Children and Adolescents

The Food and Drug Administration (FDA) directed Eli Lilly (Lilly) to revise the labeling for Strattera to include a boxed warning and additional warning statements regarding an increased risk of suicidal thinking in children and adolescents being treated with this drug. In addition, a Medication Guide will be prepared to provide directly to patients, their families, and caregivers information about the risks mentioned above. The Medication Guide is intended to be distributed by the pharmacist with each prescription or refill of a medication.

Strattera is currently approved in the United States to treat ADHD in children, adolescents, and adults. Strattera has not been studied in children under 6 years of age.

This information reflects FDA's current analysis of data available to FDA concerning this drug. FDA intends to update this sheet when additional information or analyses become available.

Recommendations

Pediatric patients being treated with Strattera should be closely observed for clinical worsening, as well as agitation, irritability, suicidal thinking or behaviors, and unusual changes in behavior, especially during the initial few months of a course of drug therapy, or at times of dose changes, either increases or decreases. This monitoring should include daily observation by families and caregivers and frequent contact with the physician.

Data Summary

The increased risk of suicidal thinking for this drug in children and adolescents was identified in a combined analysis of 12 short-term (6-18 weeks) placebo-controlled trials (11 in ADHD and 1 in enuresis). These 12 trials involved a total of over 2200 patients, including 1357 receiving Strattera and 851 receiving placebo. The analysis showed a greater risk of suicidal thinking during the first few months of treatment in those receiving Strattera. The average risk of suicidal thinking was about 4 per thousand patients treated with Strattera compared to no events in placebo-treated patients. There was 1 suicide attempt among these approximately 2200 patients, occurring in a patient treated with Strattera. A similar analysis in adult patients treated with Strattera for either ADHD or major depressive disorder (MDD) found no increased risk of suicidal ideation or behavior with the use of Strattera.

Approved Product Labeling

Additional Information
http://www.fda.gov/cder/drug/infopage/atomoxetine/default.htm

FDA Patient Information Sheet
http://www.fda.gov/cder/drug/infosheets/patient/atomoxetinePIS.pdf

Report serious adverse events to FDA's MedWatch at 1-800-FDA-1088;or www.fda.gov/medwatch/report/hcp.htm