

Dexedrine Label Reflects Heart, Psychiatric Risks

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Warnings about sudden death, exacerbation of psychiatric illnesses, and other risks associated with dextroamphetamine use have been added to the drug's label and are highlighted in a "dear health care professional" letter issued by the drug's manufacturer last month.

In the letter, which was dated Aug. 4,

2006, GlaxoSmithKline (GSK) noted that a black box warning in the label has been updated to include the statement that "misuse of amphetamines may cause sudden death and serious cardiovascular events."

GSK manufactures Dexedrine (dextroamphetamine sulfate) Spansule sustained-release capsules and tablets. Dexedrine is approved by the Food and Drug Administration for treating attention-deficit hyperactivity disorder in pe-

diatric patients, and for narcolepsy.

The warnings section also has been updated to include information about the cardiovascular and psychiatric events that have been associated with dextroamphetamine and other central nervous system stimulants.

These revisions were made after the FDA requested that all manufacturers of CNS stimulants approved for ADHD add standardized language in the prescribing information about these risks. This ac-

tion was taken in response to recommendations made by two FDA advisory panels earlier this year.

The revised warning about serious cardiovascular deaths notes that sudden death has been reported in association with usual dosages of CNS stimulants in children and adolescents with structural cardiac abnormalities or other serious heart problems.

These drugs generally should not be used in children or adolescents with "known serious structural cardiac abnormalities, cardiomyopathy, serious heart rhythm abnormalities, or other serious cardiac problems," which may make them

Patients being considered for stimulants should be assessed for a family history of sudden death or ventricular arrhythmia, and have a physical exam to evaluate for cardiac disease.

more vulnerable to the sympathomimetic effects of stimulants, according to the warning.

The warning also notes that sudden death, stroke, and myocardial infarctions have been reported in adults on usual ADHD drug doses, and that although the role of the stimulants in

these cases is unknown, adults are at greater risk than are children of having serious cardiac problems such as cardiomyopathy.

Those patients known to have such cardiac abnormalities "should also generally not be treated with stimulant drugs," according to the dear health care professional letter.

The warning recommends that children, adolescents, or adults being considered for stimulant treatment undergo a careful history that includes assessment for a family history of sudden death or ventricular arrhythmia, and physical exam to evaluate for cardiac disease, and "should receive further cardiac evaluation if findings suggest such disease."

Also highlighted in the dear health care professional letter is information from the label on psychiatric adverse events, including statements that stimulants may exacerbate symptoms in people with a preexisting psychotic disorder and can cause the appearance of treatment emergent psychotic or manic symptoms in children and adolescents with no previous history.

The label information also notes that aggressive behavior or hostility has been associated with some drugs used to treat ADHD. ■

A copy of the letter and the revised label can be found at www.fda.gov/medwatch/safety/2006/safety06.htm#Dexedrine. Serious reactions to Dexedrine can be reported to GSK at 1-888-825-5249 or to the FDA's Medwatch program at 800-FDA-1088 (phone); www.fda.gov/medwatch, or 800-FDA-0178 (fax).

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