

QUESTIONS & ANSWERS ABOUT ADDERALL® AND ADDERALL XR®

You may be aware of the recent decision by Health Canada, the Canadian equivalent of the U.S. Food and Drug Administration (FDA), to suspend the sales of Adderall XR® (mixed salts of a single-entity amphetamine product) in Canada due to certain safety concerns. Here are some answers to questions that you may have about the safety and effectiveness of Adderall XR:

Q: Is Adderall XR still available in the US?

A: Yes, Adderall and Adderall XR are both still available in the United States.

Q: How thoroughly has the safety of Adderall XR been studied?

A: More than 20 clinical studies involving 5,200 patients have carefully evaluated the safety and efficacy of Adderall XR.

Adderall XR and stimulant medications in general are among the most studied products used in clinical psychiatry today and are the most commonly prescribed medications for ADHD. For decades, they have been used to treat the symptoms of ADHD, which include decreased ability to concentrate, impulsivity, and hyperactivity. Physicians, including experts on ADHD, continue to recommend these medications as an effective therapy for ADHD.

Q: What is the position of the U.S. Food and Drug Administration (FDA) regarding the safety and effectiveness of Adderall XR?

A: Based on its own careful review of safety reports undertaken last year, and a re-review of the reports since Health Canada's decision, the FDA reaffirmed the safety and efficacy of Adderall XR when used as recommended for the treatment of ADHD. The FDA issued a statement indicating that they do not feel that any changes are warranted to the approved use of Adderall XR at this time.

Q: Did Health Canada review different information than the FDA?

A: No. Health Canada evaluated the same safety reports as the FDA. Health Canada has not made any statement that these reported events were caused by Adderall XR.

Q: How long have Adderall and Adderall XR been used?

A: Adderall has been available for the treatment of ADHD since 1996 in the United States. Adderall XR has been available for the treatment of ADHD since 2001 in the United States. Over 40 million prescriptions have been written for Adderall or Adderall XR. In 2004 alone, more than 2 million patients in the U.S. used Adderall or Adderall XR to help manage their ADHD symptoms.

Q: How many physicians have used Adderall XR?

A: Over 200,000 doctors in the U.S. have prescribed Adderall or Adderall XR. Doctors prescribe Adderall XR more often than any other brand of ADHD medication.

Q: Have patients taking Adderall or Adderall XR experienced Sudden Unexpected Death?

A: There have been very rare reports over the last eight years of sudden, unexpected death in patients who were taking, or were thought to be taking, Adderall or Adderall XR at the time.

Q: How does this number of reports with patients taking Adderall and Adderall XR compare with that seen in the general untreated population?

A: The number of these events is no more than would be expected in the untreated general population for the same time period.

Q: Were Adderall or Adderall XR responsible for these events?

A: The FDA has not determined that the events were caused by Adderall or Adderall XR. Some patients were also taking other medications and/or had heart problems in addition to their ADHD.

Q: Have there been reports of sudden death in patients taking other ADHD medications?

A: Yes. There have also been very rare reports of death in patients who were taking other ADHD medications, including methylphenidate (Concerta[®] or Ritalin[®]) and Strattera[®]. As with Adderall XR, the cases were extremely rare, and the medications were not determined to have caused the deaths.

Q: What can you tell me about these patients?

A: Many of the patients were also taking other prescription medications and/or had heart problems in addition to their ADHD. The FDA recommends that patients who have certain heart problems, including high blood pressure, generally should not take Adderall XR. Some of these heart problems can be inherited from one of the parents and can often be diagnosed by a doctor.

As people with ADHD and their families well know, ADHD is a very real, and often debilitating, disorder if not properly diagnosed and treated. The serious consequences of untreated ADHD may include poor academic and work performance, low self-esteem and difficulty with social interactions. Only your doctor can tell you if Adderall XR is right for you or your child.

Important Safety Information for Adderall XR

The most common adverse events in pediatric trials included loss of appetite, insomnia, abdominal pain, and emotional lability. The most common adverse events in the adult trial included dry mouth, loss of appetite, insomnia, headache, and weight loss.

The effectiveness of Adderall XR for long-term use has not been systematically evaluated in controlled trials. As with other psychostimulants indicated for ADHD, there is a potential for exacerbating motor and phonic tics and Tourette's syndrome. A side effect seen with the amphetamine class is psychosis. Caution also should be exercised in patients with a history of psychosis.

Abuse of amphetamines may lead to dependence. Misuse of amphetamines may cause sudden death and serious cardiovascular adverse events. Adderall XR generally should not be used in children or adults with structural cardiac abnormalities. Adderall XR is contraindicated in patients with symptomatic cardiovascular disease, moderate to severe hypertension, hyperthyroidism and glaucoma, known hypersensitivity to this class of compounds, agitated states, history of drug abuse, or current or recent use of MAO inhibitors. Adderall XR should be prescribed with close physician supervision.

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