Canadian Agency for Drugs and Technologies in Health

COMMON DRUG REVIEW

Canadian Expert Drug Advisory Committee
Final Recommendation and Reasons for Recommendation
Plain Language Version

Mixed Amphetamine Salts (Adderall XR — Shire Canada Inc.)

Indication — Attention-Deficit Hyperactivity Disorder (ADHD)

The information contained within this plain language version of the Canadian Expert Drug Advisory Committee (CEDAC) Final Recommendation and Reasons for Recommendation about this drug is based on the information found within the corresponding technical version of the CEDAC Final Recommendation and Reasons for Recommendation.

In making its recommendation, CEDAC considered the best clinical and pharmacoeconomic evidence available, up to that time. Health care professionals and those requiring more detailed information are advised to refer to the technical version available in the CDR Drug Database *on the CADTH website (*www.cadth.ca*).*

Description of Drug

Adderall XR is a drug that consists of a combination of two types of amphetamines — drugs that are stimulants. It is approved by Health Canada for the treatment of children, teens, and adults with attention-deficit hyperactivity disorder, more commonly known as ADHD. CEDAC previously considered Adderall XR in November 2004 for treatment of children with ADHD and recommended "do not list." CEDAC considered the drug again because it is now approved for teens and adults with ADHD and because there are more recent studies of Adderall XR in children.

Dose

The recommended dose for Adderall XR ranges from 5 mg to 30 mg taken once daily. Adderall XR is available in capsules in 5 mg, 10 mg, 15 mg, 20 mg, 25 mg, and 30 mg strengths.

CEDAC Recommendation

CEDAC recommended that Adderall XR not be listed for coverage by the publicly funded drug plans in Canada that participate in the Common Drug Review.

© 2009 CADTH

CEDAC Reasons for the Recommendation

- There is not enough evidence to show that Adderall XR works better than other less expensive stimulant drugs, such as methylphenidate and dexamphetamine, which are already available to manage ADHD.
- Studies have shown some improvements in patients with ADHD treated with Adderall XR compared with placebo, but these studies are short — less than four weeks long. Because there are no longer studies of Adderall XR, it is not known whether the drug improves quality of life, grades in school, or long-term behaviour of people with ADHD.
- Adderall XR has not been shown to offer good value for money to the publicly funded drug plans when used first (before trying any other drugs for ADHD). CEDAC considered whether or not Adderall XR should be funded for patients in whom methylphenidate or dexamphetamine, which are less costly drugs for ADHD, are not working well enough. However, it is not known how well Adderall XR would work in these patients. CEDAC felt it was important that studies be done on patients who have not responded to treatment with methylphenidate or dexamphetamine.

Summary of CEDAC Considerations

In addition to the information that CEDAC considered in 2004, CEDAC looked at the following additional studies of Adderall XR.

Children

- Two studies were of Adderall XR in children. One of these looked at Adderall XR compared with atomoxetine, another drug used to manage ADHD. (Atomoxetine is commonly known by its brand name, Strattera.) This study lasted 18 days and included 215 children who had ADHD. The second study compared Adderall XR with placebo. It included 52 children and lasted for three weeks.
- Children taking Adderall XR had improved behaviour, attention, and better performance on a ten-minute math test compared with children taking placebo. Children taking Adderall XR were also more likely to be rated as “very much improved” or “much improved” by their doctors or other health professionals than children taking placebo.
- When children taking Adderall XR were compared with children taking Strattera, the children taking Adderall XR showed greater improvements in their behaviour, attention, and ten-minute math test scores. They were also more likely to be rated as “very much improved” or “much improved” by their doctors or other health professionals. There were no differences in the quality of life of children taking Adderall XR compared with those taking Strattera.

Teens and Adults

- Two studies looked at Adderall XR in the management of ADHD in teens and adults, one study in each age group. Both studies compared Adderall XR with placebo, and both lasted for four weeks.
- Both teens and adults taking Adderall XR showed an improvement in the measures of their symptoms of ADHD compared with those taking placebo. More teens and adults taking Adderall XR were more likely to be seen as “very much improved” or “much improved” by their doctors or other health professionals. There were no differences in the quality of life of those taking Adderall XR compared with those taking placebo.

© 2009 CADTH

In the four studies (in children and teens and adults) that were considered, there was no difference in the number of serious side effects with Adderall XR compared with placebo or Strattera. In the adult study, more people withdrew from the study because of side effects with Adderall XR than with placebo. The most common side effects of Adderall XR were difficulties in sleeping, loss of appetite, and weight loss.

Adderall XR at any dose costs $2.75 each day. This is more expensive than some drugs commonly used to manage ADHD (e.g., immediate release methylphenidate that costs $0.25 to $0.50 for 20 mg to 40 mg per day) and similar to the cost of other drugs for ADHD (e.g., extended release methylphenidate that costs $2.09 to $3.38 for 18 mg to 54 mg per day or dexamphetamine that costs $0.52 to $6.26 for 5 mg to 60 mg per day).

Background on CEDAC

CEDAC is a committee of the Canadian Agency for Drugs and Technologies in Health (CADTH). The committee is made up of drug evaluation experts and public members. CEDAC provides recommendations about whether or not drugs should be listed for coverage through the participating publicly funded drug plans; however, the individual drug plans make their own decision about whether or not to cover a drug.

In making its recommendations, CEDAC decides if the drug under review ought to be covered by the participating public drug plans based on an evidence-informed review of the medication's effectiveness and safety, and based on an assessment of its cost-effectiveness in comparison with other available treatments.

The CEDAC Final Recommendation and Reasons for Recommendation neither takes the place of a medical professional providing care to a particular patient, nor is it intended to replace professional advice. CADTH is not legally responsible for any damages arising from the use or misuse of any information contained in or implied by the contents of this document.

The statements, conclusions, and views expressed herein do not necessarily represent the views of Health Canada, the federal government, any provincial or territorial government, or any pharmaceutical manufacturer.

The manufacturer has reviewed this document and has not requested the deletion of any confidential information.

© 2009 CADTH