

ATOMOXETINE

A New Treatment for Attention Deficit Hyperactivity Disorder



On Nov. 26, 2002, the U.S. Food and Drug Administration approved atomoxetine as a “safe and effective” medication for the treatment of attention deficit hyperactivity disorder (ADHD) in children, adolescents, and adults.

What is atomoxetine?

Atomoxetine (brand name Strattera) is a new class of medication for the treatment of ADHD.

How does atomoxetine work?

Atomoxetine is a selective norepinephrine re-uptake inhibitor. It appears to work by blocking or slowing the reabsorption of norepinephrine, one of the key neurotransmitters in the brain.

How effective is atomoxetine?

In six placebo-controlled studies, atomoxetine was shown to improve the primary symptoms of ADHD in children, adolescents, and adults.

Aren't there already effective medications for ADHD?

Yes. But no one treatment is appropriate for all patients with ADHD. The decision about which treatment makes most sense for a particular person should be based on a careful review and discussion of all available information. Moreover, it is always helpful to have a range of medications that are effective for treating specific conditions. It is likely that some people may respond to one medication and not another. Differing side effects and dosage schedules may also make a particular medication more or less appropriate for a specific patient.

How is atomoxetine different from the currently available treatments for ADHD?

Unlike the existing FDA-approved treatments for ADHD, atomoxetine is not classified as a controlled substance. Based on the research available thus far, atomoxetine appears to be effective when given either once or twice a day. In addition, since it is not a controlled substance, the medication can be refilled by phone, and physicians are allowed to distribute patient samples.

What are the side effects?

In experimental trials, atomoxetine has generally been well-tolerated. The most common side effects in children and adolescents were decreased appetite, nausea, vomiting, tiredness, and upset stomach. In adults, the most common side effects were problems sleeping, dry mouth, decreased appetite, upset stomach, nausea, vomiting, dizziness, problems urinating, and sexual difficulties.

How extensively has atomoxetine been studied?

Thus far, over 4,000 children, adolescents, and adults have been treated with atomoxetine as part of research studies. Clinical trials have lasted as long as three years. Additional studies are currently underway.

Background Information on ADHD

ADHD is a well-described, well-researched condition that affects approximately 5% of all children and adolescents. It is characterized by problems with attention, activity, and impulsivity. The diagnosis is based on specific criteria developed as a result of extensive national studies. Symptoms must also be present for at least six months, and they must be interfering with the child's life at home, in school, or with friends.

ADHD is more common in boys than in girls. The signs and symptoms must be present by the age of 7. For some children, the symptoms of ADHD subside as they grow older. However, research indicates that as many as 50% will continue experiencing difficulties well into adulthood.

Despite widespread professional consensus regarding the specific diagnostic criteria, ADHD is not always an easy diagnosis to make. Other conditions, including anxiety disorders, learning disabilities, bipolar disorder, conduct disorder, and depression can all present with similar signs and symptoms. It is important to obtain a comprehensive evaluation before deciding on any specific treatment plan.

Fortunately, effective treatments are available to help children with ADHD. Treatment will often include working with the individual child as well as the family and/or

school. It may also include medication. Research clearly indicates that medication can be very helpful in treating ADHD, but medication alone is rarely the appropriate intervention for complex child psychiatric disorders.

Without proper treatment, ADHD can have significant long-term consequences for a child. Children frequently fall behind in schoolwork and experience difficulties with their peers. The condition can also affect a child's self-esteem. As children grow older, problems with antisocial behavior and depression are common. Adolescents with untreated ADHD are also more likely to have problems with substance abuse. However, careful research has demonstrated that comprehensive treatment, including, when appropriate, treatment with medication, eliminates this increased risk.

Existing treatments for ADHD, including medications such as methylphenidate, or Ritalin, have been shown to be extremely effective at reducing the core symptoms of the disorder. There has been extensive research documenting the safety and efficacy of methylphenidate, and it is also an FDA-approved treatment for ADHD in children and

adolescents, although not in adults. Other medications, including some antidepressants, are also used in the treatment of ADHD, although these medications are not specifically FDA-approved for this purpose.

The good news is that most children, adolescents, and adults with ADHD can and do respond well to treatment. At least 70% of patients improve significantly with appropriate intervention and follow-up. But we also know that treatment is most effective when problems are recognized early and patients receive the comprehensive help and support they really need.

The information in this fact sheet has been supplied by David Fassler, M.D. a child and adolescent psychiatrist practicing in Burlington, Vt. Dr. Fassler, a clinical associate professor in the University of Vermont's Department of Psychiatry, is also a trustee of the American Psychiatric Association (www.psych.org) and a member of the Work Group on Consumer Issues of the American Academy of Child and Adolescent Psychiatry (www.aacap.org).

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