Strattera® (atomoxetine HCl) Fact Sheet

Product Description: Strattera is a new class of medication for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) in children, adolescents and adults. Strattera is a selective norepinephrine reuptake inhibitor. Unlike previous FDA-approved treatments for ADHD, Strattera is not a controlled substance and is not a stimulant under the Controlled Substances Act.

Mechanism of Action: While scientists don't know exactly how Strattera reduces ADHD symptoms, they believe Strattera works by blocking or slowing reabsorption of norepinephrine, a brain chemical – or "neurotransmitter" – considered important in regulating attention, impulsivity and activity levels. This keeps more norepinephrine at work in the small gaps between neurons in the brain. By blocking the norepinephrine transporters at these gaps, more norepinephrine is available to help pass impulses from one neuron to another.

Benefits: Strattera is the first new class of medication for the treatment of ADHD in decades. Strattera is also the first medication specifically indicated for the treatment of ADHD in adults. Most adults with ADHD go undiagnosed and/or untreated, in part because it is perceived as a childhood disorder, and in part because of concerns about giving controlled substances to adults. Stimulants have been the most frequently prescribed medications for the treatment of ADHD. However, for some patients, stimulants do not work or may cause unacceptable side effects. Because it's not a controlled substance, Strattera offers the convenience of phone-in refills, as well as samples from a physician.

Dosage: In the children, adolescents, and adults studied in clinical trials, Strattera was effective when given either once or twice a day. Strattera is available in 5, 10, 18, 25, 40 and 60 mg capsules.

Efficacy: In six placebo-controlled studies, Strattera significantly improved overall core symptoms of ADHD in children, adolescents and adults.[1,2] (There are 18 widely recognized core symptoms of ADHD that fall under the categories of inattention and hyperactivity/impulsivity.) In addition, children treated with Strattera demonstrated significant improvement on measures of family and social functioning related to ADHD.

Safety and Tolerability: In clinical trials, Strattera was generally well-tolerated. Strattera should not be taken at the same time as, or within two weeks of taking, a monoamine oxidase inhibitor, or by patients with narrow angle glaucoma. Patients with a history of high or low blood pressure, increased heart rate, or any heart or blood vessel disease should tell their doctor before taking Strattera. Strattera has not been tested in children less than six years of age. Some children may lose weight when starting treatment with Strattera. As with all ADHD medications, growth should be monitored during treatment.

Most people in clinical studies who experienced side effects were not bothered enough to stop using Strattera. 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 or vomiting, dizziness, problems urinating and sexual side effects.

Approval Status: The U.S. Food and Drug Administration approved Strattera on November 26, 2002, judging it safe and effective for the treatment of ADHD in children, adolescents and adults.

Clinical Studies: More than 4,000 children, adolescents and adults have taken Strattera during short- and long-term clinical trials, some lasting as long as three years. Ongoing studies of Strattera include long-term efficacy/relapse prevention, once-daily dosing, adult studies, and a two-year study of long-term effects of treatment in more than 800 patients.

For full prescribing information visit www.Strattera.com.

[1] Spencer T, Biederman J, Wilens T, Prince J, Hatch M, Jones J, Harding M, Faraone SV, Seidman L (1998), Effectiveness and tolerability of tomoxetine in adults with attention deficit hyperactivity disorder. *Am J Psychiatry* 155:693-5.

[2] Heiligenstein JH, Spencer TJ, Faries DE, Biederman J, Kratochvil C, Conners CF (2000), Efficacy of atomoxetine vs. placebo in pediatric outpatients with ADHD. Poster presented at the 47th Annual Meeting of the American Academy of Child & Adolescent Psychiatry, New York, NY October 2000.

AT25625 3000024284