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Strattera Controlled Symptoms of ADHD with Minimal Effect on Sleep

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Comparative Data Showed Benefit Over Stimulant Treatment

Twice daily treatment with Strattera® (atomoxetine HCl), approved for the treatment of attention-deficit/hyperactivity disorder (ADHD), showed children with ADHD fell asleep faster (12.1 minutes relative to baseline versus 39.2 minutes relative to baseline, p<.001) compared to three-times daily treatment with methylphenidate, according to study results presented at the Associated Professional Sleep Societies meeting. The results were based on comparisons before treatment and during treatment.

Parent and child diaries also showed that children on Strattera had less difficulty getting out of bed in the morning versus children taking methylphenidate. Additionally, parent diaries showed children on Strattera were less irritable compared to methylphenidate.

"Sleep difficulties related to methylphenidate therapy can represent a considerable source of concern for patients and families of children with ADHD," said study author Judith Owens, M.D., MPH, Child and Family Psychiatry, Rhode Island Hospital, Providence, R.I. "The availability of an effective medication option that may help patients to fall asleep faster is useful in the treatment of ADHD."

Although patients had a greater decrease in the number of wake bouts (episodes of wakening) with methylphenidate (-1.3 for Strattera patients compared to baseline versus -4.4 for methylphenidate patients compared to baseline, p=.011), Strattera allowed patients to sleep longer relative to methylphenidate (-15.3 minutes compared to baseline vs.. -29.6 minutes compared to baseline, p=.016).

A total of 85 children were randomized to a double blind, cross over trial in which participants were treated with Strattera or methylphenidate for seven weeks and then alternated therapy. A portion of three patients' data was removed as they had difficulty utilizing the monitors. After collecting baseline measures, children were treated with Strattera (mean dose 1.56 mg/kg) or methylphenidate (mean dose 1.12 mg/kg) for seven weeks each, separated by a washout period. Relative to baseline, the data indicated that methylphenidate increased time to sleep onset significantly more than Strattera -12.1 minutes for Strattera vs.. 39.2 minutes for methylphenidate, p<.001. For children and adolescents, maximum approved label dosing for Strattera is 1.4 mg/kg/day or 100 mg, whichever is less.

"When kids get the sleep they need, they may be less irritable. This may impact a variety of settings - at home, at school, and in social situations," said A.J. Allen, M.D., Ph.D., Lilly Research Laboratories, Eli Lilly and Company.

About ADHD

ADHD affects 3-7 percent of school-age children and manifests itself in levels of attention, concentration, activity, distractibility, and impulsivity that are inappropriate to the child's age.[1] In addition, 60 percent of children with the disorder carry their symptoms into adulthood.[2] Experts estimate 4 percent of adults in the United States, more than 8 million people, have ADHD.[3,4]

About Strattera

The U.S. Food and Drug Administration approved Strattera on Nov. 26, 2002, for the treatment of ADHD in children, adolescents and adults.

Strattera, a selective norepinephrine reuptake inhibitor, works differently than other FDA-approved treatments for the disorder, all of which are stimulants. It is not known precisely how Strattera reduces ADHD symptoms, but scientists believe it works by blocking or slowing reabsorption of norepinephrine, a chemical in the brain considered important in regulating attention, impulsivity and activity levels. This keeps more norepinephrine at work in the spaces between neurons in the brain. Improved efficiency in the norepinephrine system is associated with improvement in symptoms of ADHD (Pliska, 1996).

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 or in geriatric patients. 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 in medical studies were upset stomach, decreased appetite, nausea and vomiting, dizziness, tiredness and mood swings. In adults, the most common side effects were constipation, dry mouth, nausea, decreased appetite, dizziness, problems sleeping, sexual side effects, problems urinating and menstrual cramps.

About Eli Lilly and Company

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For full prescribing information visit www.strattera.com.

This press release contains forward-looking statements about the potential of Strattera for the treatment of ADHD and reflects Lilly's current beliefs. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of commercialization. There is also no guarantee that the product will continue to be commercially successful. For further discussion of these and other risks and uncertainties, see Lilly's filings with the United States Securities and Exchange Commission. Lilly undertakes no duty to update forward-looking statements.

References

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2. Schweitzer JB, et al. Attention-deficit/hyperactivity disorder. Med Clin of North Am. 2001; 85(3):757-777.
3. Murphy K, Barkley, RA. *J Atten disord*. 1996; 1:147-161.
4. United States Census Summary File; 2000.

Strattera, 25 mg Dosage