NAMI MINNESOTA
National Alliance on Mental Illness

Fact Sheet

800 Transfer Road, Suite 31, St. Paul, MN 55114 Tel: 651-645-2948 or 888-NAMI-HELPS Fax: 651-645-7379 www.namihelps.org

Strattera (atomoxetine HCl)

FDA ALERT (09/2005): Suicidal thinking in children and teens

In September of 2005, the FDA issued a warning that Strattera increased the risk of suicidal ideation in short-term studies in children or adolescents with Attention-Deficit/Hyperactivity Disorder (ADHD). Children or adolescents who are started on therapy with Strattera should be monitored closely for suicidality (suicidal thinking and behavior), clinical worsening, or unusual changes in behavior.

FDA ALERT (12/2004): Severe liver injury

Strattera can cause liver damage in rare cases. Call your doctor right away if you have itching, dark urine, yellow skin/eyes, upper right-sided abdominal tenderness, or unexplained "flu-like" symptoms.

Brand and Generic Names:

- Brand name = Strattera®

Capsules:

10 mg (white)

18 mg (white and orange)

25 mg (blue and white)

40 mg (blue)

60 mg (blue and orange)

80 mg (brown and white)

100 mg (brown)

- Generic name = atomoxetine

What is Strattera® and what does it treat?

Atomoxetine is a prescription medication that is used to treat children over 6 years old, adolescents, and adults with attention-deficit hyperactivity disorder (ADHD). It is the first and so far, only, medicine FDA approved for ADHD that is not a stimulant.

ADHD is associated with severe inattention, hyperactivity, and impulsivity that interfere with an individual's ability to function in school, at work, or in social settings. Examples of functionally impairing ADHD symptoms include making careless mistakes, losing things necessary for tasks, the inability to sit still and focus, and interrupting or intruding on others.

Adults have similar symptoms but display less hyperactivity compared to children. Adults with ADHD may be more prone to procrastination, becoming easily frustrated and taking on many tasks at once while accomplishing none of them. A person may have severe inattention without hyperactivity or impulsivity and still meet criteria for the diagnosis of ADHD. Atomoxetine may be less likely to exacerbate or cause tics compared to stimulant medications. It may also be effective in children with ADHD who also have anxiety.

Atomoxetine is used as an adjunct to psychological, educational, social, and other remedial measures (i.e., appropriate educational placement, appropriate career selection) in the treatment of ADHD. Scientific literature shows that atomoxetine is effective in decreasing inattention and hyperactive/impulsive symptoms as measured on various rating scales. Atomoxetine is an option for those who have not responded to or cannot tolerate stimulants, or in those who may benefit from a medication with low to no abuse potential. Lastly, the response to atomoxetine treatment has not been studied for more than one year in children and two years in adolescents.

What is the most important information I should know about Strattera®?

- It may take several weeks before you feel better. Do not stop taking this medication without talking to your doctor first.
- Individuals with schizophrenia, schizoaffective disorder, bipolar disorder or any other brain disorder associated with psychotic symptoms should avoid using atomoxetine because it may make these conditions worse.
- Atomoxetine should also be avoided in those with high blood pressure, blood vessel problems, blood disorders, heart disease, tachycardia (rapid heart rate), and narrow angle glaucoma (eye disease) since it can worsen these conditions as well.

- Individuals taking atomoxetine should avoid becoming dehydrated since dehydration increases the risk of hypotension (decreased blood pressure) caused by this medicine.

Atomoxetine may cause dizziness and drowsiness. Individuals taking atomoxetine should avoid driving, operating machinery, or performing other hazardous activities until they know how this medicine affects them.

- The safety and effectiveness has not been established for this medicine for children less than 6 years of age. Atomoxetine may also increase the risk of suicidal thinking in children and adolescents with ADHD. Close monitoring for signs of suicidality (increased aggression, hostility, agitation, irritability, suicidal thinking or behaviors) in individuals started on atomoxetine therapy is essential.
- Atomoxetine should not be used at the same time or within two weeks of taking a medication class called monoamine oxidase inhibitors (MAOIs), usually used to treat depression. MAOIs include phenelzine (Nardil), tranylcypromine (Parnate), selegiline (EMSAM) and isocarboxazid (Marplan). Some medications also have MAOI-like activity, such as linezolid (Zyvox), and should be avoided as well. Using atomoxetine within two weeks of, or at the same time as MAOIs can result in dangerously high blood pressure that can be fatal.
- Atomoxetine is not a stimulant medication and therefore is not considered a controlled substance by the Drug Enforcement Agency (DEA). Atomoxetine has not been shown to have abuse potential. However, like all medications, atomoxetine should only be used as directed.

Are there specific concerns about Strattera® and pregnancy?

- No adequate and well-controlled studies have been conducted in pregnant women. Atomoxetine should not be used during pregnancy unless the potential benefit justifies the potential risk to the fetus. The effect of atomoxetine on labor and delivery in humans is unknown. Atomoxetine and/or its metabolites were excreted in the milk of rats. It is not known if atomoxetine is excreted in human milk. Caution should be exercised if atomoxetine is administered to a nursing woman.

What should I discuss with my healthcare provider before taking Strattera®?

- Symptoms that are most bothersome to you about your condition
- If you have thoughts of suicide
- Medications you have taken in the past to treat ADHD, mood or thought organization
- All other medications you are currently taking and any medication allergies you have
- Any medication side effects you may have experienced in the past or are currently experiencing
- If you have or have had:

- liver problems, high blood pressure, heart problems, irregular heartbeat, low blood pressure, depression, bipolar disorder or other psychiatric disorders
- If you are trying to become pregnant, are already pregnant, or are breast-feeding.
- If you use any illegal drugs or alcohol.

How should I take Strattera®?

- Take atomoxetine exactly as prescribed by your doctor. Take each dose with a full glass (8 ounces) of water.
- Atomoxetine may be taken with or without food.
- Atomoxetine should be taken regularly to get the most benefit.
- Swallow capsule whole; do not open capsule to "sprinkle" on food
- Store all medications, including atomoxetine, away from moisture and heat.

What happens if I miss a dose of Strattera®?

- If you miss a dose, take the missed dose as soon as you remember during the same day. If you do not remember until the next day, skip the missed dose and take only the doses scheduled for that day. Do not take more than the prescribed total daily amount of atomoxetine in any 24-hour period.

What should I avoid while taking Strattera®?

You should not drink alcohol or take illegal drugs while taking atomoxetine. The effects of these substances and atomoxetine are unpredictable and may also reduce the effectiveness of the medicine.

What happens if I overdose with Strattera®?

- Symptoms of atomoxetine overdose may include sleepiness, drowsiness, agitation, hyperactivity, abnormal behavior, upset stomach, diarrhea, blurred vision, fast heartbeat and dry mouth. Seizures and abnormal heart rhythms may also occur with overdose.Seek emergency medical attention immediately if overdose, whether intentional or accidental, occurs.

What are the possible side effects of Strattera®?

Common side effects include upset stomach, nausea, or vomiting, decreased appetite, constipation, dry mouth, insomnia, decreased libido or sexual side effects, menstrual cycle changes, hot flushes, or sweating, fatigue, unusual tiredness or weakness, feeling of sluggishness, sedation, sleepiness, irritability or mood swings

Contact your healthcare provider immediately if there is an allergic reaction (difficulty breathing, closing of the throat, swelling of the lips, tongue, or face, hives)

In rare cases, atomoxetine has been associated with liver damage. Contact your healthcare provider if you notice dark urine, have flu-like symptoms, persistent anorexia, itchiness, abdominal pain, or yellowing of the eyes or skin.

Are there any risks for taking Strattera® for long periods of time?

- There has been some evidence that atomoxetine can suppress normal height and weight patterns in children/adolescents. Gains in height and weight tend to lag behind in those who are taking atomoxetine for about the first 9-12 months of therapy. There is some evidence that height and weight may rebound back to expected measurements, however this may not happen for all children/adolescents. The decrease in weight in children taking atomoxetine was 0.87kg over two years. The decrease in height over two years in children/adolescents taking atomoxetine was 0.44 cm. Scientific literature shows evidence that the decrease in growth velocity in children taking methylpheidate over 3 to 4 years was approximately 1 cm per year for the first three years of methylphenidate therapy. It is recommended that height and weight are monitored throughout treatment with atomoxetine.

What other medications interact with Strattera®?

Antidepressants

Newer antidepressants – Some of the newer antidepressants can increase the effects of Stattera, including Prozac (fluoxetine) and Paxil (paroxetine)

Blood pressure medications

Blood pressure medications can become less effective when used with atomoxetine. Monitor blood pressure closely and let your healthcare provider know if you have a problem with high blood pressure.

Medications for the heart

Cardioquin or Dura-Tabs (quinidine) can increase the effects of atomoxetine.

Let your healthcare provider know if you are taking this medication.

Medications for asthma/difficulty breathing

Albuterol can increase the risk of high blood pressure and also increased heart rate (pulse).

Medications used for ADHD or weight loss or to increase alertness

Taking atomoxetine with other medications that have stimulant effects can increase the effects and adverse effects of atomoxetine. These include: amphetamine, Dexedrine (dextroamphetamine), Adderall (mixed amphetamine salts), methylphenidate (Ritalin, Methylin, Concerta, Daytrana patch), dexmethylphenidate (Focalin), Meridia (sibutramine), phenylephrine, guarana, and caffeine.

Other

Atomoxetine should not be taken together with or within 14 days of taking a monoamine oxidase inhibitor (MAOI). MAOIs include: Nardil (phenelzine), Parnate (tranylcypromine), EMSAM (selegiline) and isocarboxazid (Marplan). Linezolid (Zyvox) also has MAOI-like properties and should not be used together with atomoxetine therapy. Coadministering atomoxetine within 2 weeks of the above medications can result in dangerously high blood pressure that can be fatal.

Many other medications may interact with atomoxetine. Talk to your doctor or pharmacist before taking any prescription or over-the-counter medicines, including herbal products, during treatment with atomoxetine.

How long does it take for Strattera® to work?

It may take 4 - 8 weeks after an effective dose is reached for atomoxetine to reach maximum effectiveness. However, improvements in some symptoms may occur sooner.

By Jessica M. Fung, Pharm.D, MBA
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NAMI wishes to thank the College of Psychiatric and Neurological Pharmacists for producing this fact sheet.

For further information. Please contact the pharmaceutical company listed below.

Eli Lilly and Company	Lilly Corporate Center Indianapolis, IN 46285	800-545-5979	www.lilly.com

Free or low-cost medications provided by pharmaceutical companies

Some pharmaceutical companies offer medication assistance programs to low-income individuals and families. These programs typically require a doctor's consent and proof of financial status. They may also require that you have either no health insurance, or no prescription drug benefit through your health insurance. Please contact the pharmaceutical company directly for specific eligibility requirements and application information.

Strattera Rx Assistance Program: 1-800-545-6962