

[FDA APPROVED PPI FOR NDA 21-411/S-001
ATTACHMENT TO APPROVAL LETTER]

NL 3740 AMP

INFORMATION FOR PATIENTS OR THEIR PARENTS OR CAREGIVERS

STRATTERA[®] (atomoxetine HCl)

Read this information before you start taking STRATTERA (Stra-TAIR-a). Read this information you get each time you get more STRATTERA. There may be new information. This information does not take the place of talking to your doctor about your medical condition or treatment.

What is STRATTERA?

STRATTERA is a non-stimulant medicine used to treat Attention-Deficit/Hyperactivity Disorder (ADHD). STRATTERA contains atomoxetine hydrochloride, a selective norepinephrine reuptake inhibitor. Your doctor has prescribed this medicine as part of an overall treatment plan to control your symptoms of ADHD.

What is ADHD?

ADHD has 3 main types of symptoms: inattention, hyperactivity, and impulsiveness. Symptoms of inattention include not paying attention, making careless mistakes, not listening, not finishing tasks, not following directions, and being easily distracted. Symptoms of hyperactivity and impulsiveness include fidgeting, talking excessively, running around at inappropriate times, and interrupting others. Some patients have more symptoms of hyperactivity and impulsiveness while others have more symptoms of inattentiveness. Some patients have all 3 types of symptoms.

Symptoms of ADHD in adults may include a lack of organization, problems starting tasks, impulsive actions, daydreaming, daytime drowsiness, slow processing of information, difficulty learning new things, irritability, lack of motivation, sensitivity to criticism, forgetfulness, low self-esteem, and excessive effort to maintain some organization. The symptoms shown by adults who primarily have attention problems but not hyperactivity have been commonly described as Attention-Deficit Disorder (ADD).

Many people have symptoms like these from time to time, but patients with ADHD have these symptoms more than others their age. Symptoms must be present for at least 6 months to be certain of the diagnosis.

Who should NOT take STRATTERA?

Do not take STRATTERA if:

- you took a medicine known as a monoamine oxidase inhibitor (MAOI) in the last 2 weeks. An MAOI is a medicine sometimes used for depression and other mental problems. Some names of MAOI medicines are Nardil[®] (phenelzine sulfate) and Parnate[®] (tranylcypromine sulfate). Taking STRATTERA with an MAOI could cause serious side effects or be life-threatening.
- you have narrow angle glaucoma, an eye disease.
- you are allergic to STRATTERA or any of its ingredients. The active ingredient is atomoxetine. The inactive ingredients are listed at the end of this leaflet.

What should I tell my doctor before taking STRATTERA?

Talk to your doctor before taking STRATTERA if you:

- have or had liver problems. You may need a lower dose.
- have high blood pressure. STRATTERA can increase blood pressure.
- have problems with your heart or an irregular heartbeat. STRATTERA can increase heart rate (pulse).
- have low blood pressure. STRATTERA can cause dizziness or fainting in people with low blood pressure.

Tell your doctor about all the medicines you take or plan to take, including prescription and non-prescription medicines, dietary supplements, and herbal remedies. Your doctor will decide if you can take STRATTERA with your other medicines.

Certain medicines may change the way your body reacts to STRATTERA. These include medicines used to treat depression [like Paxil[®] (paroxetine) and Prozac[®] (fluoxetine)], and certain other medicines (like quinidine). Your doctor may need to change your dose of STRATTERA if you are taking it with these medicines.

STRATTERA may change the way your body reacts to oral or intravenous albuterol (or drugs with similar actions), but the effectiveness of these drugs will not be changed. Talk with your doctor before taking STRATTERA if you are taking albuterol.

How should I take STRATTERA?

- Take STRATTERA according to your doctor's instructions. This is usually taken 1 or 2 times a day (morning and late afternoon/early evening).
- You can take STRATTERA with or without food.
- If you miss a dose, take it as soon as possible, but do not take more than your total daily dose in any 24-hour period.
- Taking STRATTERA at the same time each day may help you remember.
- STRATTERA is available in several dosage strengths: 10, 18, 25, 40, and 60 mg.

Call your doctor right away if you take more than your prescribed dose of STRATTERA.

Other important safety information about STRATTERA

Use caution when driving a car or operating heavy machinery until you know how STRATTERA affects you.

Talk to your doctor if you are:

- pregnant or planning to become pregnant
- breast-feeding. We do not know if STRATTERA can pass into your breast milk.

What are the possible side effects of STRATTERA?

The most common side effects of STRATTERA used in teenagers and children over 6 years old are:

- upset stomach
- decreased appetite
- nausea or vomiting
- dizziness
- tiredness
- mood swings

Weight loss may occur after starting STRATTERA. It is not known if growth will be slowed in children who use STRATTERA for a long period of time. Your doctor will watch your weight and height. If you are not growing or gaining weight as expected, your doctor may change your treatment of STRATTERA.

The most common side effects of STRATTERA used in adults are:

- constipation
- dry mouth
- nausea
- decreased appetite
- dizziness
- problems sleeping
- sexual side effects
- problems urinating
- menstrual cramps

Stop taking STRATTERA and call your doctor right away if you get swelling or hives. STRATTERA can cause a serious allergic reaction in rare cases.

This is not a complete list of side effects. Talk to your doctor if you develop any symptoms that concern you.

General advice about STRATTERA

STRATTERA has not been studied in children under 6 years old.

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use STRATTERA for a condition for which it was not prescribed. Do not give STRATTERA to other people, even if they have the same symptoms you have.

This leaflet summarizes the most important information about STRATTERA. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information on STRATTERA that is written for health professionals. You can also call 1-800-Lilly-Rx (1-800-545-5979) or visit our website at www.strattera.com.

What are the ingredients in STRATTERA?

Active ingredient: atomoxetine.

Inactive ingredients: pregelatinized starch, dimethicone, gelatin, sodium lauryl sulfate, FD&C Blue No. 2, synthetic yellow iron oxide, titanium dioxide, and edible black ink.

Store STRATTERA at room temperature.

This patient information summary has been approved by the US Food and Drug Administration.

Literature issued XXXX

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www.strattera.com

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