



## Patient Information Sheet

### Atomoxetine (marketed as Strattera)

This is a summary of the most important information about Strattera. For more information, talk to your healthcare professional.

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#### FDA ALERT [09/2005] Suicidal Thinking in Children and Teens

- **Strattera may increase thoughts of suicide or suicide attempts in children and teens.**
- **Call your child's healthcare professional right away if your child or teen has:**
  - **new or increased thoughts of suicide**
  - **changes in mood or behavior including becoming irritable or anxious**

**The label for Strattera is being revised to include the above warnings.**

*This information reflects FDA's current analysis of data available to FDA concerning this drug. FDA intends to update this sheet when additional information or analyses become available.*

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#### What Is Strattera?

Strattera is used to treat a condition called Attention-Deficit with Hyperactivity Disorder (ADHD) in children, teens, and adults. Strattera has not been studied in children under 6 years old.

#### Who Should Not Take Strattera?

You should not take Strattera if you:

- are taking a medicine called a Monoamine Oxidase Inhibitor (MAOI). Do not take Strattera for at least 2 weeks after you stop taking a MAOI. Do not take a MAOI for at least 2 weeks after you stop taking Strattera.
- have an eye disease called narrow angle glaucoma

#### What Are The Risks?

*The following are the major potential risks and side effects of Strattera. However, this list is not complete.*

The following are the major potential risks and side effects of Strattera therapy:

- **Suicidal thoughts or actions:** Strattera may increase thoughts of suicide or suicide attempts in infrequent cases. Call your doctor right away if you become irritable or anxious or have other mood changes, or if you have thoughts of suicide.
- **Liver Damage:** Strattera can cause liver damage in rare cases. Call your doctor right away if you have itching, dark urine, yellow skin or eyes, upper right-sided stomach area pain, or unexplained "flu-like" symptoms.
- **Weight Loss/Slowed Growth:** Some people may lose weight while being treated with Strattera. It is not known if growth will be slowed in children who use Strattera for a long time. Height and weight should be watched in children who are taking Strattera.
- **Impaired Motor Skills:** Do not drive or operate dangerous machines until you know how Strattera affects you.

#### Some common side effects that may occur with Strattera in children include:

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

#### Some common side effects that may occur with Strattera in adults include:

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





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These are **not** all of the side effects reported with Strattera. Your healthcare professional can give you a more complete list of side effects.

- have a problem with depression or suicidal thinking.

#### What Should I Tell My Healthcare Professional?

**Before you start taking Strattera**, tell your healthcare professional if you:

- have or had liver problems. You may need a lower dose of Strattera.
- 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.
- are trying to become pregnant, are already pregnant, or are breast-feeding.

#### Can other Medicines or Food Affect Strattera?

Strattera and certain other medicines can interact with each other. Tell your healthcare professional about all the medicines you take including prescription and non-prescription medicines, vitamins, and herbal supplements. Some medicines may affect how Strattera works or Strattera may affect how your other medicines work. Know the medicines you take. Keep a list of them with you to show your healthcare professional.

