

Child/Teen ADHD

# A parent's guide to getting a good start with Strattera

What to expect when beginning treatment



**strattera**<sup>®</sup>  
atomoxetine HCl

*Lilly*



# Welcome

Your child or teen has been prescribed Strattera to help manage symptoms of Attention-Deficit/Hyperactivity Disorder (ADHD). Strattera is a non-stimulant prescription medicine approved to treat ADHD. It may help manage the symptoms of ADHD. Strattera is part of a total treatment program.

Your child can face different challenges throughout the day because of ADHD. Many children with ADHD have a hard time completing homework in the evenings. Teens may have difficulty staying focused in their part-time job. And your child may struggle with not interrupting in social settings. It can be very frustrating for your child...and for you.

This guide helps your child get off to a good start with Strattera. It explains:

- How Strattera helps treat ADHD symptoms
- How to take Strattera
- What to expect when your child takes Strattera
- Important safety information about Strattera

If you have any questions about treatment with Strattera, be sure to talk with your child's healthcare provider.

*In some children and teens, Strattera increases the risk of suicidal thoughts. Call your healthcare provider right away if your child has thoughts of suicide or sudden changes in mood or behavior, especially at the beginning of treatment or after a change in dose.*

Please see Important Safety Information, including Warning, on pages 11 and 12, and FDA Medication Guide and full Prescribing Information enclosed.

# ADHD symptoms

*It is estimated that 2 million children in the United States have ADHD. This means that in a classroom of 25 to 30 students, it is likely that at least one student will have ADHD.*

*ADHD symptoms are grouped into 3 patterns of behavior. At home, at school, and with family and friends, your child may show signs of being:*

## Inattentive

- Has trouble paying attention to detail
- Is disorganized
- Often loses things
- Has trouble starting and finishing tasks
- Does not listen well

## Impulsive

- Speaks out of turn
- Interrupts
- Has a hard time waiting

## Hyperactive

- Is too active
- Cannot sit still
- Talks constantly
- Is always on the go

These are some or all of the symptoms your child may experience. Think about the symptoms you would most like to see improve as your child or teen begins treatment with Strattera.

# How Strattera can help

*Some medicines for ADHD work quickly, last for a while, and wear off later in the day. Strattera begins to improve symptoms gradually, and can provide continuous relief for your child's ADHD symptoms for a full 24 hours.*

## **When your child takes Strattera as prescribed, Strattera may help him or her:**

- Become more focused and able to pay attention
- Listen better
- Be more organized and lose fewer things
- Start and finish homework, projects, and chores
- Wait more patiently
- Interrupt less
- Act and speak less impulsively

Strattera is a non-stimulant prescription medicine approved to treat the symptoms of ADHD.

All medicines for ADHD, including Strattera, can have side effects. The most common side effects of Strattera in children and teens were upset stomach, decreased appetite, nausea or vomiting, dizziness, tiredness, and mood swings. See page 5 for tips on how to manage side effects.

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# How to take Strattera

- Your child should take Strattera exactly as directed by his or her healthcare provider.
- Your child should take Strattera with a meal to help reduce nausea.
- Your child should take Strattera at the same time every day.
- Strattera is usually taken once each day in the morning. But your child's healthcare provider may decide it is best for him or her to take a dose that is taken twice a day—once in the morning and once in the late afternoon or evening.
- If your child misses a dose of Strattera, he or she should take it as soon as you remember that day. If your child misses a day of Strattera, do not double his or her dose the next day. Just skip the day he or she missed.
- Do not open Strattera capsules. Your child must swallow each capsule whole.
- Do not stop your child from taking Strattera without talking to his or her healthcare provider.

## What are the possible side effects of Strattera?

The most common side effects in children and teenagers were upset stomach, decreased appetite, nausea or vomiting, dizziness, tiredness, mood swings, and slowing of growth in children. Other serious side effects include allergic reactions including swelling, hives, or other allergic reactions.

# Managing side effects

*All medicines for ADHD, including Strattera, can have side effects. If your child has side effects, be sure to talk with his or her healthcare provider.*

Here are some tips to help your child manage some common side effects that he or she may experience on Strattera.

## **Nausea**

While your child's body is getting used to Strattera, he or she may have an upset stomach. If this happens, it can help to administer Strattera with food.

## **Feeling tired**

Some children or teens who take Strattera feel tired during the day. If this happens to your child, his or her healthcare provider may suggest that you change the time of day that your child takes Strattera.

*This is not a complete list of side effects. If you have any questions or concerns, be sure to talk with your child's healthcare provider.*

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# What to expect with Strattera

*Following these 3 steps can help get your child off to the best possible start with Strattera.*

## Step 1: Setting goals with Strattera

*When your child starts treatment with Strattera, it is important to set some small personalized goals of the things that impact the different aspects of his or her life the most. Things you both would like to see improve.*

It is important to create goals that can be tracked as your child continues treatment so that you can see your child's progress and assess how Strattera is working. Choose 3 or 4 things in your child's daily life that have been impacted the most by his or her ADHD symptoms. List them below. Some examples are listed to help you get started.

Goal
<i>Example: I want to lose my favorite hat fewer than 3 times a week</i>
<i>Example: I want to finish the majority of my book reports on time</i>

## Step 2: Getting started and gradual improvement

*One of the keys to success with Strattera is working with your child's healthcare provider to find the right dose for your child. Your child will likely start Strattera at a low dose. This gives his or her body a chance to get used to the medicine. Over the next few weeks, you, your child, and your child's healthcare provider will work together to reach the dose of Strattera that will benefit your child the most.*

*After your child reaches the right dose, give Strattera some time to work. Your child might begin to notice small changes after taking Strattera for a few weeks. But keep in mind that symptom improvement with Strattera is gradual and takes time. If Strattera works for your child, your child should see improvement in his or her symptoms in about 4 to 6 weeks after reaching the right dose.*

In some children and teens, Strattera increases the risk of suicidal thoughts. Call your child's healthcare provider right away if he or she has thoughts of suicide or develops new psychological symptoms such as abnormal thoughts/behaviors and/or extreme elevated or irritable moods while taking Strattera.

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*Also think about subtle changes your child may have experienced. Perhaps they haven't accomplished all their goals, but he or she might have seen some improvement with certain things happening less frequently. You may also want to ask your child's teacher for input on their progress.*

*It is important to know that Strattera does not work for everyone. So if he or she has not seen any improvement, you should talk to your child's healthcare provider and see if Strattera is the right medicine or if you should consider a different treatment option for your child.*



## Step 3: Tracking your child's progress

*Continue checking to see whether your child has achieved the goals you both set.*

### Goal

*When your child first started treatment*

*You both set goals for things you wanted to see improve (page 6). Place them in the left side of this table.*

### Record your progress

*After 4 to 6 weeks at your child's ideal dose*

*Use the right side of this table to note changes in your child's behavior and interactions. Again, consider talking with your child's teacher as he or she may see changes that you don't. Share these notes with your child's healthcare provider so he or she may determine your child's progress.*

### Example goal tracker

Goal	Record progress
<i>I want to lose my favorite hat fewer than 3 times a week</i>	<i>I lost my hat only 2 times this week</i>
<i>I want to finish the majority of my book reports on time</i>	<i>I have finished 2 reports on time this week</i>

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## Your child's goal tracker

Goal	Record progress

Keep checking the progress your child has made in achieving his or her goals and see if there has been a gradual improvement.

# Important safety information

*Strattera is indicated for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) in children aged 6 and older, teens, and adults.*

## **What should I talk about with the healthcare provider?**

In some children and teens, Strattera increases the risk of suicidal thoughts. A combined analysis of 12 studies of Strattera showed that in children and teens, 4 out of every 1000 patients developed suicidal thoughts, although no suicides occurred. A similar analysis in adults treated with Strattera did not reveal an increased risk of suicidal thoughts. Call your doctor right away if your child has thoughts of suicide or sudden changes in mood or behavior, especially at the beginning of treatment or after a change in dose.

## **What other important information should I discuss with the healthcare provider?**

In rare cases, Strattera can cause liver injury. Call your doctor right away if your child has itching, right upper belly pain, dark urine, yellow skin or eyes, or unexplained flu-like symptoms.

Tell your doctor if your child has any heart problems, heart defects, high blood pressure, or a family history of these problems. Your doctor should check them carefully for heart problems before starting Strattera. Call your doctor right away if there are any signs of heart problems such as chest pain, shortness of breath, or fainting while taking Strattera. Rarely, sudden death has been reported in patients who have heart problems or heart defects. There have also been rare reports of stroke and heart attack.

Please see the FDA Medication Guide and full Prescribing Information enclosed.

Tell your doctor about any family history of bipolar illness (manic-depressive illness) or suicidal thoughts or actions before starting Strattera. Call the doctor right away if your child develops new psychological symptoms such as abnormal thoughts/behaviors and/or extreme elevated or irritable moods while taking Strattera.

Erections that won't go away (priapism) have occurred rarely during treatment with Strattera. If your child has an erection that lasts more than 4 hours, seek medical help right away.

### **Who should not take Strattera?**

Strattera should not be taken by your child if:

- They are taking or have taken within the past 14 days an anti-depression medicine called a monoamine oxidase inhibitor or MAOI.
- Have an eye problem called glaucoma.
- Are allergic to anything in Strattera.

### **Can Strattera be taken with other medicines?**

Tell your doctor about all the medicines that your child takes including prescription and nonprescription medicines, vitamins, and herbal supplements. Strattera and some medicines may interact with each other and cause serious side effects. Your doctor will decide whether Strattera can be taken with other medicines.

### **What are the possible side effects of Strattera?**

The most common side effects in children and teenagers were upset stomach, decreased appetite, nausea or vomiting, dizziness, tiredness, mood swings, and slowing of growth in children. Other serious side effects include allergic reactions including swelling, hives, or other allergic reactions.



*You are taking important steps to treat your child's ADHD symptoms. Gradually your child may be better able to focus in school, at home, and in social situations.*

To learn more, go to:

**[www.strattera.com](http://www.strattera.com)**

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**Personal Notes**

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You are taking important steps to treat your child's ADHD symptoms. Gradually your child may be better able to focus in school, at home, and during social situations.

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# MEDICATION GUIDE

## STRATTERA® (Stra-TAIR-a) (atomoxetine hydrochloride)

Read the Medication Guide that comes with STRATTERA® before you or your child starts taking it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your doctor about your treatment or your child's treatment with STRATTERA.

### **What is the most important information I should know about STRATTERA?**

The following have been reported with use of STRATTERA:

#### **1. Suicidal thoughts and actions in children and teenagers:**

Children and teenagers sometimes think about suicide, and many report trying to kill themselves. Results from STRATTERA clinical studies with over 2200 child or teenage ADHD patients suggest that some children and teenagers may have a higher chance of having suicidal thoughts or actions. Although no suicides occurred in these studies, 4 out of every 1000 patients developed suicidal thoughts. Tell your child or teenager's doctor if your child or teenager (or there is a family history of):

- has bipolar illness (manic-depressive illness)
- had suicide thoughts or actions before starting STRATTERA

#### **The chance for suicidal thoughts and actions may be higher:**

- early during STRATTERA treatment
- during dose adjustments

#### **Prevent suicidal thoughts and action in your child or teenager by:**

- paying close attention to your child or teenager's moods, behaviors, thoughts, and feelings during STRATTERA treatment
- keeping all follow-up visits with your child or teenager's doctor as scheduled

#### **Watch for the following signs in your child or teenager during STRATTERA treatment:**

- anxiety
- agitation
- panic attacks
- trouble sleeping
- irritability
- hostility
- aggressiveness
- impulsivity
- restlessness
- mania
- depression
- suicide thoughts

Call your child or teenager's doctor right away if they have any of the above signs, especially if they are new, sudden, or severe. Your child or teenager may need to be closely watched for suicidal thoughts and actions or need a change in medicine.

#### **2. Severe liver damage:**

STRATTERA can cause liver injury in some patients. Call your doctor right away if you or your child has the following signs of liver problems:

- itching
- right upper belly pain
- dark urine

- yellow skin or eyes
- unexplained flu-like symptoms

#### **3. Heart-related problems:**

- **sudden death in patients who have heart problems or heart defects**
- **stroke and heart attack in adults**
- **increased blood pressure and heart rate**

Tell your doctor if you or your child has any heart problems, heart defects, high blood pressure, or a family history of these problems. Your doctor should check you or your child carefully for heart problems before starting STRATTERA.

Your doctor should check your blood pressure or your child's blood pressure and heart rate regularly during treatment with STRATTERA.

**Call your doctor right away if you or your child has any signs of heart problems such as chest pain, shortness of breath, or fainting while taking STRATTERA.**

#### **4. New mental (psychiatric) problems in children and teenagers:**

- new psychotic symptoms (such as hearing voices, believing things that are not true, being suspicious) or new manic symptoms

**Call your child or teenager's doctor right away about any new mental symptoms** because adjusting or stopping STRATTERA treatment may need to be considered.

### **What Is STRATTERA?**

STRATTERA is a selective norepinephrine reuptake inhibitor medicine. It is used for the treatment of attention deficit and hyperactivity disorder (ADHD). STRATTERA may help increase attention and decrease impulsiveness and hyperactivity in patients with ADHD.

STRATTERA should be used as a part of a total treatment program for ADHD that may include counseling or other therapies.

STRATTERA has not been studied in children less than 6 years old.

### **Who should not take STRATTERA?**

#### **STRATTERA should not be taken if you or your child:**

- are taking or have taken within the past 14 days an anti-depression medicine called a monoamine oxidase inhibitor or MAOI. Some names of MAOI medicines are Nardil® (phenelzine sulfate), Parnate® (tranylcypromine sulfate) and Emsam® (selegiline transdermal system).
- have an eye problem called narrow angle glaucoma
- are allergic to anything in STRATTERA. See the end of this Medication Guide for a complete list of ingredients.

**STRATTERA may not be right for you or your child. Before starting STRATTERA tell your doctor or your child's doctor about all health conditions (or a family history of) including:**

- have or had suicide thoughts or actions
- heart problems, heart defects, irregular heart beat, high blood pressure, or low blood pressure
- mental problems, psychosis, mania, bipolar illness, or depression
- liver problems

Tell your doctor if you or your child is pregnant, planning to become pregnant, or breastfeeding.

### **Can STRATTERA be taken with other medicines?**

**Tell your doctor about all the medicines that you or your child takes including prescription and nonprescription medicines, vitamins, and herbal supplements.** STRATTERA and some medicines may interact with each other and cause serious side effects.

Your doctor will decide whether STRATTERA can be taken with other medicines.

**Especially tell your doctor if you or your child takes:**

- asthma medicines
- anti-depression medicines including MAOIs
- blood pressure medicines
- cold or allergy medicines that contain decongestants

Know the medicines that you or your child takes. Keep a list of your medicines with you to show your doctor and pharmacist.

**Do not start any new medicine while taking STRATTERA without talking to your doctor first.**

**How should STRATTERA be taken?**

- **Take STRATTERA exactly as prescribed. STRATTERA comes in different dose strength capsules.** Your doctor may adjust the dose until it is right for you or your child.
- **Do not chew, crush, or open the capsules.** Swallow STRATTERA capsules whole with water or other liquids. Tell your doctor if you or your child cannot swallow STRATTERA whole. A different medicine may need to be prescribed.
- Avoid touching a broken STRATTERA capsule. Wash hands and surfaces that touched an open STRATTERA capsule. If any of the powder gets in your eyes or your child's eyes, rinse them with water right away and call your doctor.
- STRATTERA can be taken with or without food.
- STRATTERA is usually taken once or twice a day. Take STRATTERA at the same time each day to help you remember. If you miss a dose of STRATTERA, take it as soon as you remember that day. If you miss a day of STRATTERA, do not double your dose the next day. Just skip the day you missed.
- From time to time, your doctor may stop STRATTERA treatment for a while to check ADHD symptoms.
- Your doctor may do regular checks of the blood, heart, and blood pressure while taking STRATTERA. Children should have their height and weight checked often while taking STRATTERA. STRATTERA treatment may be stopped if a problem is found during these check-ups.
- **If you or your child takes too much STRATTERA or overdoses, call your doctor or poison control center right away, or get emergency treatment.**

**What are possible side effects of STRATTERA?**

See **"What is the most important information I should know about STRATTERA?"** for information on reported suicidal thoughts and actions, other mental problems, severe liver damage, and heart problems.

**Other serious side effects include:**

- serious allergic reactions (call your doctor if you see swelling, hives, or experience other allergic reactions)
- slowing of growth (height and weight) in children
- problems passing urine including:
  - trouble starting or keeping a urine stream
  - cannot fully empty the bladder

**Common side effects in children and teenagers include:**

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

**Common side effects in adults include:**

- constipation
- dry mouth
- nausea
- decreased appetite
- dizziness
- trouble sleeping
- sexual side effects
- menstrual cramps
- problems passing urine

**Other information for children, teenagers, and adults:**

- Erections that won't go away (priapism) have occurred rarely during treatment with STRATTERA. If you have an erection that lasts more than 4 hours, seek medical help right away. Because of the potential for lasting damage, including the potential inability to have erections, priapism should be evaluated by a doctor immediately.
- STRATTERA may affect your ability or your child's ability to drive or operate heavy machinery. Be careful until you know how STRATTERA affects you or your child.
- Talk to your doctor if you or your child has side effects that are bothersome or do not go away.

This is not a complete list of possible side effects. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**How should I store STRATTERA?**

- Store STRATTERA in a safe place at room temperature, 59 to 86°F (15 to 30°C).
- **Keep STRATTERA and all medicines out of the reach of children.**

**General information about STRATTERA**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. 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 condition. It may harm them.

This Medication Guide 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 about STRATTERA that was written for healthcare professionals. For more information about STRATTERA call 1-800-Lilly-Rx (1-800-545-5979) or visit [www.strattera.com](http://www.strattera.com).

**What are the ingredients in STRATTERA?**

**Active ingredient:** atomoxetine hydrochloride.

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

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*This Medication Guide has been approved by the US Food and Drug Administration.*

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