

17.5 Priapism

Rare postmarketing cases of priapism, defined as painful and nonpainful penile erection lasting more than 4 hours, have been reported for pediatric and adult patients treated with STRATTERA. The parents or guardians of pediatric patients taking STRATTERA and adult patients taking STRATTERA should be instructed that priapism requires prompt medical attention.

17.6 Ocular Irritant

STRATTERA is an ocular irritant. STRATTERA capsules are not intended to be opened. In the event of capsule content coming in contact with the eye, the affected eye should be flushed immediately with water, and medical advice obtained. Hands and any potentially contaminated surfaces should be washed as soon as possible.

17.7 Drug-Drug Interaction

Patients should be instructed to consult a physician if they are taking or plan to take any prescription or over-the-counter medicines, dietary supplements, or herbal remedies.

17.8 Pregnancy

Patients should be instructed to consult a physician if they are nursing, pregnant, or thinking of becoming pregnant while taking STRATTERA.

17.9 Food

Patients may take STRATTERA with or without food.

17.10 Missed Dose

If patients miss a dose, they should be instructed to take it as soon as possible, but should not take more than the prescribed total daily amount of STRATTERA in any 24-hour period.

17.11 Interference with Psychomotor Performance

Patients should be instructed to use caution when driving a car or operating hazardous machinery until they are reasonably certain that their performance is not affected by atomoxetine.

Literature revised June 3, 2009

Eli Lilly and Company

Indianapolis, IN 46285, USA

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PV 6264 AMP

www.strattera.com

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.

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.

Nardil[®] is a registered trademark of Pfizer Inc.

Parnate[®] is a registered trademark of GlaxoSmithKline.

Emsam[®] is a registered trademark of Somerset Pharmaceuticals Inc.

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

Patient Information revised July 23, 2008

Eli Lilly and Company

Indianapolis, IN 46285, USA

www.strattera.com

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PV 5854 AMP

PACKAGE LABEL - STRATTERA 10 mg bottle of 30

NDC 0002-3227-30

30 Capsules

No. 3227

strattera[®]

atomoxetine HCl

Rx only

10 mg

Each capsule equivalent to 10 mg atomoxetine

Do not use if Lilly inner seal is missing or broken.

www.strattera.com

Lilly

PACKAGE LABEL - STRATTERA 18 mg bottle of 30

NDC 0002-3238-30

30 Capsules

No. 3238

strattera[®]

atomoxetine HCl

Rx only

18 mg

Each capsule equivalent to 18 mg atomoxetine

Do not use if Lilly inner seal is missing or broken.

www.strattera.com

Lilly

PACKAGE LABEL - STRATTERA 25 mg bottle of 30

NDC 0002-3228-30

30 Capsules

No. 3228

strattera[®]

atomoxetine HCl

Rx only

25 mg

Each capsule equivalent to 25 mg atomoxetine

Do not use if Lilly inner seal is missing or broken.

www.strattera.com

Lilly

PACKAGE LABEL - STRATTERA 40 mg bottle of 30

NDC 0002-3229-30

30 Capsules

No. 3229

strattera[®]

atomoxetine HCl

Rx only

40 mg

Each capsule equivalent to 40 mg atomoxetine

Do not use if Lilly inner seal is missing or broken.

www.strattera.com

Lilly

PACKAGE LABEL - STRATTERA 60 mg bottle of 30

NDC 0002-3239-30

30 Capsules

No. 3239

strattera[®]

atomoxetine HCl

Rx only

60 mg

Each capsule equivalent to 60 mg atomoxetine

Do not use if Lilly inner seal is missing or broken.

www.strattera.com

Lilly

PACKAGE LABEL - STRATTERA 80 mg bottle of 30

NDC 0002-3250-30

30 Capsules

No. 3250

strattera[®]

atomoxetine HCl

Rx only

80 mg

Each capsule equivalent to 80 mg atomoxetine

Do not use if Lilly inner seal is missing or broken.

www.strattera.com

Lilly

PACKAGE LABEL - STRATTERA 100 mg bottle of 30

NDC 0002-3251-30

30 Capsules

No. 3251

strattera[®]

atomoxetine HCl

Rx only

100 mg

Each capsule equivalent to 100 mg atomoxetine

Do not use if Lilly inner seal is missing or broken.

www.strattera.com

Lilly

PACKAGE CARTON - STRATTERA 10 mg bottle of 7, sample

Bottle of 7 CAPSULES

PU 3227 007

Rx only

FREE SAMPLE

strattera[®]
atomoxetine HCl
10 mg
Each capsule equivalent to 10 mg atomoxetine
www.strattera.com
Lilly

PACKAGE CARTON - STRATTERA 18 mg bottle of 7, sample

Bottle of 7 CAPSULES

PU 3238 007

Rx only

FREE SAMPLE

strattera[®]
atomoxetine HCl

18 mg

Each capsule equivalent to 18 mg atomoxetine

www.strattera.com

Lilly

PACKAGE CARTON - STRATTERA 25 mg bottle of 7, sample

Bottle of 7 CAPSULES

PU 3228 007

Rx only

FREE SAMPLE

strattera[®]
atomoxetine HCl

25 mg

Each capsule equivalent to 25 mg atomoxetine

www.strattera.com

Lilly

PACKAGE CARTON - STRATTERA 40 mg bottle of 7, sample

Bottle of 7 CAPSULES

PU 3229 007

Rx only

FREE SAMPLE

strattera[®]
atomoxetine HCl

40 mg

Each capsule equivalent to 40 mg atomoxetine

www.strattera.com

Lilly

PACKAGE CARTON - STRATTERA 60 mg bottle of 7, sample

Bottle of 7 CAPSULES

PU 3239 007

Rx only

FREE SAMPLE

strattera[®]
atomoxetine HCl

60 mg

Each capsule equivalent to 60 mg atomoxetine

www.strattera.com

Lilly

PACKAGE CARTON - STRATTERA 80 mg bottle of 7, sample

Bottle of 7 CAPSULES

PU 3250 007

Rx only

FREE SAMPLE

strattera[®]

atomoxetine HCl

80 mg

Each capsule equivalent to 80 mg atomoxetine

www.strattera.com

Lilly

PACKAGE CARTON - STRATTERA (Titration Blister Pack), sample

5 x 10 mg Capsules PU 3227

5 x 18 mg Capsules PU 3238

5 x 25 mg Capsules PU 3228

15 x 40 mg Capsules PU 3229

strattera[®]

atomoxetine HCl

FREE SAMPLE

This sample pack is recommended for children and adolescents whose weight is

63 – 74 lbs (28.6 – 33.3 kg).

See full Prescribing Information to determine appropriate therapeutic dose.

Rx only

10 mg

Each capsule equivalent to 10 mg atomoxetine

18 mg

Each capsule equivalent to 18 mg atomoxetine

25 mg

Each capsule equivalent to 25 mg atomoxetine

40 mg

Each capsule equivalent to 40 mg atomoxetine

www.strattera.com

Lilly

PACKAGE CARTON - STRATTERA (Titration Blister Pack), sample

5 x 18 mg Capsules PU 3238

5 x 25 mg Capsules PU 3228

5 x 40 mg Capsules PU 3229

15 x 60 mg Capsules PU 3239

strattera[®]

atomoxetine HCl

FREE SAMPLE

This sample pack is recommended for children and adolescents whose weight is

94 – 110 lbs (42.9 – 50.0 kg).

See full Prescribing Information to determine appropriate therapeutic dose.

Rx only

Each capsule equivalent to 18 mg atomoxetine

Each capsule equivalent to 25 mg atomoxetine

Each capsule equivalent to 40 mg atomoxetine

Each capsule equivalent to 60 mg atomoxetine

www.strattera.com

Lilly

PACKAGE CARTON - STRATTERA (Titration Blister Pack), sample

5 x 25 mg Capsules PU 3228

5 x 40 mg Capsules PU 3229

5 x 60 mg Capsules PU 3239

15 x 80 mg Capsules PU 3250

strattera[®]

atomoxetine HCl

FREE SAMPLE

This sample pack is recommended for children and adolescents whose weight is 126 – 147 lbs (57.2 – 66.7 kg) and adults.

See full Prescribing Information to determine appropriate therapeutic dose.

Rx only

25 mg

Each capsule equivalent to 25 mg atomoxetine

40 mg

Each capsule equivalent to 40 mg atomoxetine

60 mg

Each capsule equivalent to 60 mg atomoxetine

80 mg

Each capsule equivalent to 80 mg atomoxetine

www.strattera.com

Lilly

Revised: 06/2009

Distributed by: Eli Lilly and Company