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## Atomoxetine

pronounced as (at' oh mox e teen)

### IMPORTANT WARNING:

Studies have shown that children and teenagers with attention-deficit hyperactivity disorder (ADHD; more difficulty focusing, controlling actions, and remaining still or quiet than other people who are the same age) who take atomoxetine are more likely to think about killing themselves than children and teenagers with ADHD who do not take atomoxetine.

While your child is taking atomoxetine, you should watch his or her behavior very carefully, especially at the beginning of treatment and any time his or her dose is increased or decreased. Your child may develop serious symptoms very suddenly, so it is important to pay attention to his or her behavior every day. Ask other people who spend a lot of time with your child, such as brothers, sisters, and teachers to tell you if they notice changes in your child's behavior. Call your child's doctor right away if your child experiences any of these symptoms: acting more subdued or withdrawn than usual; feeling helpless, hopeless, or worthless; new or worsening depression; thinking or talking about harming or killing him- or herself or planning or trying to do so; extreme worry; agitation; panic attacks; difficulty falling asleep or staying asleep; irritability; aggressive or violent behavior; acting without thinking; extreme increase in activity or talking; frenzied, abnormal excitement; or any other sudden or unusual changes in behavior.

Your child's doctor will want to see your child often while he or she is taking atomoxetine, especially at the beginning of his or her treatment. Your child's doctor may also want to speak with you or your child by telephone from time to time. Be sure that your child keeps all appointments for office visits or telephone conversations with his or her doctor.

Your doctor or pharmacist will give you the manufacturer's patient information sheet (Medication Guide) when you begin treatment with atomoxetine and each time you refill your prescription. Read the information carefully and ask your doctor or pharmacist if you have any questions. You can also visit the Food and Drug Administration (FDA) website

(<http://www.fda.gov/Drugs> [<http://www.fda.gov/Drugs>] ) or the manufacturer's website to obtain the Medication Guide.

Talk to your doctor about the risks of giving atomoxetine to your child, of using other treatments for your child's condition, and of not treating your child's condition.

## **Why is this medication prescribed?**

Atomoxetine is used as part of a total treatment program to increase the ability to pay attention and decrease impulsiveness and hyperactivity in children and adults with ADHD. Atomoxetine is in a class of medications called selective norepinephrine reuptake inhibitors. It works by increasing the levels of norepinephrine, a natural substance in the brain that is needed to control behavior.

## **How should this medicine be used?**

Atomoxetine comes as a capsule to take by mouth. It is usually taken either once a day in the morning, or twice a day in the morning and late afternoon or early evening. Atomoxetine may be taken with or without food. Take atomoxetine at around the same time(s) every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take atomoxetine exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Swallow atomoxetine capsules whole; do not open, chew, or crush them. If a capsule is accidentally broken or opened, wash away the loose powder with water right away. Try not to touch the powder and be especially careful not to get the powder in your eyes. If you do get powder in your eyes, rinse them with water right away and call your doctor.

Your doctor will probably start you on a low dose of atomoxetine and increase your dose after at least 3 days. Your doctor may increase your dose again after 2–4 weeks. You may notice improvement in your symptoms during the first week of your treatment, but it may take up to one month for you to feel the full benefit of atomoxetine.

Atomoxetine may help to control the symptoms of ADHD but will not cure the condition. Continue to take atomoxetine even if you feel well. Do not stop taking atomoxetine without talking to your doctor.

## **Other uses for this medicine**

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

## What special precautions should I follow?

### Before taking atomoxetine,

- tell your doctor and pharmacist if you are allergic to atomoxetine, any other medications, or any of the ingredients in atomoxetine capsules.
- Some medications should not be taken with atomoxetine. Other medications may cause dosing changes or extra monitoring when taken with atomoxetine. Make sure you have discussed any medications you are currently taking or plan to take before starting atomoxetine with your doctor and pharmacist. Before starting, stopping, or changing any medications while taking atomoxetine, please get the advice of your doctor or pharmacist..
- Tell your doctor or pharmacist if you are taking the following medications or have stopped taking them within the past two weeks: isocarboxazid (Marplan), phenelzine (Nardil), selegiline (Eldepryl, Emsam, Zelapar), and tranylcypromine (Parnate).
- tell your doctor if you have or have ever had glaucoma (an eye disease that may cause vision loss), or pheochromocytoma (a tumor on a small gland near the kidneys). Your doctor will probably tell you not to take atomoxetine.
- tell your doctor if anyone in your family has or has ever had an irregular heartbeat or has died suddenly. Tell your doctor if you have recently had a heart attack and if you have or have ever had a heart defect, high blood pressure, an irregular heartbeat, hardening of the arteries, heart or blood vessel disease, or other heart problems. Your doctor will examine you to see if your heart and blood vessels are healthy. Your doctor will probably tell you not to take atomoxetine if you have a heart condition or if there is a high risk that you may develop a heart condition.
- tell your doctor if you or anyone in your family has or has ever had depression, bipolar disorder (manic depressive disorder; a condition that causes episodes of depression, episodes of frenzied, abnormal excitement and other abnormal moods), or has ever thought about or attempted suicide. Also tell your doctor if you have or have ever had seizures, or liver disease.
- tell your doctor if you are pregnant, plan to become pregnant, or are breast-feeding. If you become pregnant while taking atomoxetine, call your doctor.
- you should know that atomoxetine may make you drowsy. Do not drive a car or operate machinery until you know how this medication affects you.
- you should know that atomoxetine may cause dizziness, lightheadedness, and fainting when you get up too quickly from a lying position. To avoid this problem, get out of bed slowly, resting your feet on the floor for a few minutes before standing up.
- you should know that atomoxetine should be used as part of a total treatment program for ADHD, which may include counseling and special education. Make sure to follow all of your doctor's and/or therapist's instructions.
- you should know that your blood pressure may increase during your treatment with atomoxetine. Your doctor will monitor your blood pressure during your treatment.

## What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

## **What should I do if I forget a dose?**

Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one. Do not take more than the prescribed daily amount of atomoxetine in 24 hours.

## **What side effects can this medication cause?**

**Atomoxetine may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:**

- heartburn
- nausea
- vomiting
- loss of appetite
- weight loss
- constipation
- stomach pain
- gas
- dry mouth
- excessive tiredness
- dizziness
- headache
- mood swings
- decreased sex drive or ability
- difficulty urinating
- painful or irregular menstrual periods
- muscle pain
- sweating
- hot flashes
- unusual dreams
- burning or tingling in the hands, arms, feet, or legs

**Some side effects can be serious. If you experience any of the following symptoms, or those listed in the IMPORTANT WARNING or SPECIAL PRECAUTIONS**

**section, call your doctor immediately:**

- fast or pounding heartbeat
- chest pain
- shortness of breath
- slow or difficult speech
- dizziness or faintness
- weakness or numbness of an arm or leg
- itchy skin
- dark urine
- yellowing of your skin or eyes
- flu-like symptoms
- pain in the upper right part of your stomach
- swelling of the face, throat, tongue, lips, eyes, hands, feet, ankles, or lower legs
- hoarseness
- difficulty swallowing or breathing
- hives
- rash
- abnormal thoughts
- hallucinating (seeing things or hearing voices that do not exist)
- erection that lasts for several hours or longer
- seizures

Atomoxetine may slow down children's growth or weight gain. Your child's doctor will probably monitor your child carefully during his or her treatment with atomoxetine. Talk to your child's doctor about the risks of giving this medication to your child.

Atomoxetine may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>] ) or by phone (1-800-332-1088).

## What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom).

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>] ) for more information if you do not have access to a take-back program.

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

## In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>] . If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

## Symptoms of overdose may include the following:

- sleepiness
- agitation
- an increase in activity or talking
- abnormal behavior
- stomach problems
- wide pupils (black circles in the middle of the eyes)
- fast heartbeat
- dry mouth

## What other information should I know?

Keep all appointments with your doctor and the laboratory. Your doctor may order certain lab tests to check your body's response to atomoxetine.

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

## Brand names

- Strattera<sup>®</sup>

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