

MEDICATION GUIDE

Atomoxetine Capsules, USP (a" toe mox' e teen)

Read the Medication Guide that comes with atomoxetine capsules 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 atomoxetine.

What is the most important information I should know about atomoxetine capsules?

The following have been reported with use of atomoxetine:

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 atomoxetine 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 atomoxetine capsules

The chance for suicidal thoughts and actions may be higher:

- early during atomoxetine 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 atomoxetine 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 atomoxetine 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:

Atomoxetine 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 atomoxetine.

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

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 atomoxetine.

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 atomoxetine treatment may need to be considered.

What are atomoxetine capsules?

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

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

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

Who should not take atomoxetine capsules?

Atomoxetine 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 atomoxetine capsules. See the end of this Medication Guide for a complete list of ingredients.
- have or have had a rare tumor called pheochromocytoma.

Atomoxetine capsules may not be right for you or your child. Before starting atomoxetine 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
- are pregnant or plan to become pregnant. It is not known if atomoxetine will harm your unborn baby. Talk to your doctor if you are pregnant or plan to become pregnant.
 - There is a pregnancy registry for females who are exposed to ADHD medications, including atomoxetine, during pregnancy. The purpose of the registry is to collect information about the health of females exposed to atomoxetine and their baby. If you or your child becomes pregnant during treatment with atomoxetine, talk to your healthcare provider about registering with the National Pregnancy Registry of ADHD Medications at 1-866-961-2388 or visit online at <https://womensmentalhealth.org/adhdmedications/>.
- are breastfeeding or plan to breastfeed. It is not known if atomoxetine passes into your breast milk. Talk to your doctor about the best way to feed your baby if you take atomoxetine.

Can atomoxetine capsules 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.

Atomoxetine and some medicines may interact with each other and cause serious side effects. Your doctor will decide whether atomoxetine 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 atomoxetine capsules without talking to your doctor first.

How should atomoxetine capsules be taken?

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

What are possible side effects of atomoxetine capsules?

See "What is the most important information I should know about atomoxetine capsules?" 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 have trouble breathing, see swelling or 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
- sexual side effects
- problems passing urine

Other information for children, teenagers, and adults:

- Erections that won't go away (priapism) have occurred rarely during treatment with atomoxetine. 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.
- Atomoxetine may affect your ability or your child's ability to drive or operate heavy machinery. Be careful until you know how atomoxetine 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 atomoxetine capsules?

- Store atomoxetine capsules in a safe place at 20°C to 25°C (68°F to 77°F) excursions permitted from 15°C to 30°C (59°F to 86°F).
- **Keep atomoxetine capsules and all medicines out of the reach of children.**

General information about atomoxetine capsules

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use atomoxetine for a condition for which it was not prescribed. Do not give atomoxetine to other people, even if they have the same condition. It may harm them.

This Medication Guide summarizes the most important information about atomoxetine capsules. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about atomoxetine capsules that was written for healthcare professionals. For more information call Apotex Corp. at 1-800-706-5575 or visit www.apotex.com.

What are the ingredients in atomoxetine capsules?

Active ingredient: atomoxetine hydrochloride, USP.

Inactive ingredients: The capsules also contain pregelatinized starch. The capsule shells contain gelatin and titanium dioxide. The capsule shells may also contain one or more of the following: FD&C Blue No. 2 (25 mg, 40 mg, and 60 mg), iron oxide red (80 mg and 100 mg), and iron oxide yellow (18 mg, 25 mg, 40 mg, 60 mg, 80 mg and 100 mg). The capsules are imprinted with edible black ink (comprised of ammonia solution, iron oxide black, potassium hydroxide, propylene glycol, and shellac).

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

All registered trademarks in this document are the property of their respective owners.

APOTEX INC.

ATOMOXETINE CAPSULES, USP

10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg and 100 mg

Manufactured by:	Manufactured for:
Apotex Inc.	Apotex Corp.
Toronto, Ontario	Weston, Florida
Canada M9L 1T9	USA 33326

Revision: 11

Revised: April 2021

REVIEWED

By Jaime at 7:44 am, Nov 24, 2021

APPROVED

By mdlrosa at 1:50 pm, Nov 24, 2021