

MEDICATION GUIDE
APTENSIO XR® (App-ten-see-o)
(methylphenidate hydrochloride extended-release)
capsules, CII

What is the most important information I should know about APTENSIO XR?

APTENSIO XR can cause serious side effects, including:

- **Abuse and dependence.** APTENSIO XR, other methylphenidate containing medicines, and amphetamines have a high chance for abuse and can cause physical and psychological dependence. Your healthcare provider should check you or your child for signs of abuse and dependence before and during treatment with APTENSIO XR.
 - Tell your healthcare provider if you or your child have ever abused or been dependent on alcohol, prescription medicines, or street drugs.
 - Your healthcare provider can tell you more about the differences between physical and psychological dependence and drug addiction.

- **Heart-related problems, including:**

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

Your healthcare provider should check you or your child carefully for heart problems before starting treatment with APTENSIO XR. Tell your healthcare provider if you or your child have any heart problems, heart defects, high blood pressure, or a family history of these problems.

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

Call your healthcare provider or go to the nearest hospital emergency room right away if you or your child have any signs of heart problems such as chest pain, shortness of breath, or fainting during treatment with APTENSIO XR.

- **Mental (psychiatric) problems, including:**

- new or worse behavior and thought problems
- new or worse bipolar illness
- new psychotic symptoms (such as hearing voices, or seeing or believing things that are not real) or new manic symptoms

Tell your healthcare provider about any mental problems you or your child have, or about a family history of suicide, bipolar illness, or depression.

Call your healthcare provider right away if you or your child have any new or worsening mental symptoms or problems during treatment with APTENSIO XR, especially hearing voices, seeing or believing things that are not real, or new manic symptoms.

What is APTENSIO XR?

APTENSIO XR is a central nervous system (CNS) stimulant prescription medicine used for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in people 6 years of age and older. APTENSIO XR may help increase attention and decrease impulsiveness and hyperactivity in people with ADHD.

- **APTENSIO XR is not for use in children under 6 years of age.**
- **APTENSIO XR is a federally controlled substance (CII) because it contains methylphenidate that can be a target for people who abuse prescription medicines or street drugs.** Keep APTENSIO XR in a safe place to protect it from theft. Never give your APTENSIO XR to anyone else, because it may cause death or harm them. Selling or giving away APTENSIO XR may harm others and is against the law.

Do not take APTENSIO XR if you or your child are:

- allergic to methylphenidate hydrochloride or any of the ingredients in APTENSIO XR. See the end of this Medication Guide for a complete list of ingredients in APTENSIO XR.
- taking or have stopped taking within the past 14 days a medicine used to treat depression called a monoamine oxidase inhibitor (MAOI).

Before taking APTENSIO XR tell your healthcare provider about all medical conditions, including if you or your child:

- have heart problems, heart defects, high blood pressure
- have mental problems including psychosis, mania, bipolar illness, or depression, or have a family history of suicide, bipolar illness, or depression
- have circulation problems in fingers and toes
- are pregnant or plan to become pregnant. It is not known if APTENSIO XR will harm your unborn baby.
 - There is a pregnancy registry for females who are exposed to APTENSIO XR during pregnancy. The purpose of the registry is to collect information about the health of females exposed to APTENSIO XR and their baby. If you or your child becomes pregnant during treatment with APTENSIO XR, talk to your healthcare provider about registering with the National Pregnancy Registry for Psychostimulants at 1-866-961-2388.
- are breastfeeding or plan to breastfeed. APTENSIO XR passes into breast milk. Talk to your healthcare provider about the best way to feed the baby during treatment with APTENSIO XR.

Tell your healthcare provider about all the medicines that you or your child take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

APTENSIO XR and some medicines may interact with each other and cause serious side effects. Sometimes the doses of other medicines will need to be changed during treatment with APTENSIO XR. Your healthcare provider will decide whether APTENSIO XR can be taken with other medicines.

Especially tell your healthcare provider if you or your child take a medicine used to treat depression called monoamine oxidase inhibitor (MAOI).

Know the medicines that you or your child take. Keep a list of the medicines with you to show your healthcare provider and pharmacist. **Do not start any new medicine during treatment with APTENSIO XR without talking to your healthcare provider first.**

How should APTENSIO XR be taken?

- Take APTENSIO XR exactly as prescribed by your healthcare provider.
- Your healthcare provider may change the dose if needed.
- Take APTENSIO XR by mouth 1 time each day in the morning.
- APTENSIO XR can be taken with or without food but take it the same way each time.
- Swallow APTENSIO XR capsules whole, or if APTENSIO XR capsules cannot be swallowed whole, the capsules may be opened and sprinkled onto a tablespoonful of applesauce. Make sure to sprinkle all the medicine onto the applesauce. The APTENSIO XR dose should not be divided.
 - swallow all the applesauce and medicine mixture without chewing right away or within 10 minutes
 - **do not** chew the applesauce and medicine mixture
 - **do not** store applesauce and medicine mixture
- Your healthcare provider may sometimes stop APTENSIO XR treatment for a while to check ADHD symptoms.
- If a dose of APTENSIO XR is missed, do not take the dose later in the day or take an extra dose to make up for the missed dose, wait until the next morning to take the next scheduled dose.
- **In case of poisoning call your poison control center at 1-800-222-1222 or go to the nearest hospital emergency room right away.**

What should be avoided during treatment with APTENSIO XR?

Avoid drinking alcohol during treatment with APTENSIO XR. This may cause a faster release of the APTENSIO XR medicine.

What are possible side effects of APTENSIO XR?

APTENSIO XR can cause serious side effects, including:

See “**What is the most important information I should know about APTENSIO XR?**”

- **Painful and prolonged erections (priapism).** Priapism has happened in males who take products that contain methylphenidate. **If you or your child develop priapism, get medical help right away.**
- **Circulation problems in fingers and toes (peripheral vasculopathy, including Raynaud’s phenomenon).** Signs and symptoms may include:

- fingers or toes may feel numb, cool, painful
- fingers or toes may change color from pale, to blue, to red

Tell your healthcare provider if you have or your child have numbness, pain, skin color change, or sensitivity to temperature in the fingers or toes.

Call your healthcare provider right away if you have or your child have any signs of unexplained wounds appearing on fingers or toes during treatment with APTENSIO XR.

- **Slowing of growth (height and weight) in children.** Children should have their height and weight checked often during treatment with APTENSIO XR. APTENSIO XR treatment may be stopped if your child is not growing or gaining weight.

The most common side effects of APTENSIO XR in children 6 to 17 years of age include stomach pain, decreased appetite, headache, trouble sleeping.

These are not all the possible side effects of APTENSIO XR.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

You may also report side effects to Rhodes Pharmaceuticals L.P. at 1-888-827-0616.

How should I store APTENSIO XR?

- Store APTENSIO XR at room temperature between 68°F to 77°F (20°C to 25°C).
- Store APTENSIO in a safe place, like a locked cabinet. Protect from moisture.
- Dispose of remaining, unused, or expired APTENSIO XR by a medication take-back program at authorized collection sites such as retail pharmacies, hospital or clinic pharmacies, and law enforcement locations. If no take-back program or authorized collector is available, mix APTENSIO XR with an undesirable, nontoxic substance such as dirt, cat litter, or used coffee grounds to make it less appealing to children and pets. Place the mixture in a container such as a sealed plastic bag and throw away APTENSIO XR in the household trash.

Keep APTENSIO XR and all medicines out of the reach of children.

General information about the safe and effective use of APTENSIO XR.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use APTENSIO XR for a condition for which it was not prescribed. Do not give APTENSIO XR to other people, even if they have the same symptoms. It may harm them and it is against the law. You can ask your doctor or pharmacist for information about APTENSIO XR that was written for healthcare professionals.

What are the ingredients in APTENSIO XR?

Active Ingredient: methylphenidate hydrochloride

Inactive Ingredients: ammonio methacrylate copolymer, type B; colloidal silicon dioxide (added if necessary); gelatin; hypromelloses; methacrylic acid copolymer, type C; polyethylene glycol; sugar spheres; talc; titanium oxide; and triethyl citrate.

Manufactured by: Patheon Manufacturing Services LLC, Greenville, North Carolina 27834

For more information call Rhodes Pharmaceuticals L.P. (the distributor for APTENSIO XR) at 1-888-827-0616.