

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 is a federally controlled substance (CII) because it can be abused or lead to dependence. Keep APTENSIO XR in a safe place to prevent misuse and abuse. Selling or giving away APTENSIO XR may harm others, and is against the law.

Tell your doctor if you or your child have (or have a family history of) ever abused or been dependent on alcohol, prescription medicines or street drugs.

The following have been reported with use of methylphenidate hydrochloride and other stimulant medicines.

1. 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 APTENSIO XR.

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

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 APTENSIO XR.

2. Mental (Psychiatric) problems:

All Patients

- **new or worse behavior and thought problems**
- **new or worse bipolar illness**

Children and Teenagers

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

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

Call your doctor right away if you or your child have any new or worsening mental symptoms or problems while taking APTENSIO XR, especially seeing or hearing things that are not real, believing things that are not real, or are suspicious.

What Is APTENSIO XR?

APTENSIO XR is a central nervous system stimulant prescription medicine. **It is used for the treatment of attention deficit hyperactivity disorder (ADHD).** APTENSIO XR may help increase attention and decrease impulsiveness and hyperactivity in patients with ADHD.

It is not known if APTENSIO XR is safe and effective in children under 6 years of age.

Who should not take APTENSIO XR?

APTENSIO XR should not be taken 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.
- are taking or have taken within the past 14 days an anti-depression medicine called a monoamine oxidase inhibitor or MAOI.

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

- heart problems, heart defects, high blood pressure
- mental problems including psychosis, mania, bipolar illness, or depression
- circulation problems in fingers and toes
- if you are pregnant or plan to become pregnant. It is not known if APTENSIO XR will harm your unborn baby. Talk to your doctor if you are pregnant or plan to become pregnant.
- if you are breastfeeding or plan to breastfeed. APTENSIO XR passes into your breast milk. You and your doctor should decide if you will take APTENSIO XR or breastfeed.

Tell your doctor about all of 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 adjusted while taking APTENSIO XR.

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

Especially tell your doctor if you or your child takes:

- anti-depression medicines including MAOIs

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 APTENSIO XR without talking to your doctor first.

How should APTENSIO XR be taken?

- Take APTENSIO XR exactly as prescribed. Your doctor may adjust the dose until it is right for you or your child.
- Take APTENSIO XR at the same time each day.
- APTENSIO XR can be taken with or without food but take it the same way each time.
- Swallow APTENSIO XR capsules whole. Do not chew or crush the medicine inside the capsule. If you or your child cannot swallow the capsule, open it and sprinkle the medicine over a spoonful of applesauce. Swallow all of the applesauce and medicine mixture without chewing right away.
- APTENSIO XR is an extended-release capsule. It releases medicine into you or your child's body throughout the day.
- From time to time, your doctor may stop APTENSIO XR treatment for a while to check ADHD symptoms.
- Your doctor may do regular checks of the blood, heart, and blood pressure while taking APTENSIO XR.
- Children should have their height and weight checked often while taking APTENSIO XR. APTENSIO XR treatment may be stopped if a problem is found during these check-ups.
- **In case of poisoning call your poison control center at 1-800-222-1222 right away, or go to the nearest hospital emergency room.**

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?**” for information on reported heart and mental problems.
- **painful and prolonged erections (priapism)** have occurred with methylphenidate. If you or your child develop priapism, seek medical help right away. **Because of the potential for lasting damage, priapism**

should be evaluated by a doctor immediately.

- **circulation problems in fingers and toes** [Peripheral vasculopathy, including Raynaud's phenomenon]:
 - fingers or toes may feel numb, cool, painful
 - fingers or toes may change color from pale, to blue, to red

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

Call your doctor right away if you have or your child has any signs of unexplained wounds appearing on fingers or toes while taking APTENSIO XR.

- **slowing of growth (height and weight) in children**

Common side effects include:

- stomach pain
- decreased appetite
- headache
- trouble sleeping

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. Ask your doctor or pharmacist for more information.

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 in a safe place at room temperature between 68°F to 77°F (20°C to 25°C).
- Protect from moisture.
- **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 condition. It may harm them and it is against the law.

This Medication Guide summarizes the most important information about APTENSIO XR. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about APTENSIO XR that was written for healthcare professionals. For more information, you may also contact Rhodes Pharmaceuticals L.P. (the distributor for APTENSIO XR) at 1-888-827-0616.

What are the ingredients in APTENSIO XR?

Active Ingredient: methylphenidate hydrochloride

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

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

Marketed by: Rhodes Pharmaceuticals L.P., Coventry, RI 02816

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

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