

MEDICATION GUIDE ADDERALL XR® (ADD-ur-all X-R) CII

Read the Medication Guide that comes with ADDERALL XR 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 you or your child's treatment with ADDERALL XR.

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

ADDERALL XR is a stimulant medicine. The following have been reported with use of 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 have 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 ADDERALL XR.

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

2. Mental (Psychiatric) problems:

All Patients

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

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 ADDERALL XR, especially seeing or hearing things that are not real, believing things that are not real, or are suspicious.

3. 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 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 your fingers or toes.

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

What Is ADDERALL XR?

ADDERALL XR is a once daily central nervous system stimulant prescription medicine. **It is used for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).** ADDERALL XR may help increase attention and decrease impulsiveness and hyperactivity in patients with ADHD.

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

ADDERALL XR is a federally controlled substance (CII) because it can be abused or lead to dependence. Keep ADDERALL XR in a safe place to prevent misuse and abuse. Selling or giving away ADDERALL 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.

Who should not take ADDERALL XR?

ADDERALL XR should not be taken if you or your child:

- have heart disease or hardening of the arteries
- have moderate to severe high blood pressure
- have hyperthyroidism
- have an eye problem called glaucoma
- are very anxious, tense, or agitated
- have a history of drug abuse
- are taking or have taken within the past 14 days an anti-depression medicine called a monoamine oxidase inhibitor or MAOI.
- is sensitive to, allergic to, or had a reaction to other stimulant medicines

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

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

- heart problems, heart defects, or high blood pressure
- mental problems including psychosis, mania, bipolar illness, or depression
- tics or Tourette's syndrome
- liver or kidney problems
- thyroid problems
- seizures or have had an abnormal brain wave test (EEG)
- circulation problems in fingers and toes

Tell your doctor if you or your child is pregnant, planning to become pregnant, or breastfeeding.

Can ADDERALL XR be taken with other medicines?

Tell your doctor about all of the medicines that you or your child takes including prescription and non-prescription medicines, vitamins, and herbal supplements. ADDERALL 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 ADDERALL XR.

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

Especially tell your doctor if you or your child takes:

- anti-depression medicines including MAOIs
- anti-psychotic medicines
- lithium
- narcotic pain medicines
- seizure medicines
- blood thinner medicines
- blood pressure medicines
- stomach acid 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 ADDERALL XR without talking to your doctor first.

How should ADDERALL XR be taken?

- **Take ADDERALL XR exactly as prescribed.** Your doctor may adjust the dose until it is right for you or your child.
- Take ADDERALL XR once a day in the morning when you first wake up. ADDERALL XR is an extended release capsule. It releases medicine into your body throughout the day.
- Swallow ADDERALL XR capsules whole with water or other liquids. 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 immediately. Follow with a drink of water or other liquid. **Never chew or crush the capsule or the medicine inside the capsule.**
- ADDERALL XR can be taken with or without food.
- From time to time, your doctor may stop ADDERALL XR treatment for a while to check ADHD symptoms.
- Your doctor may do regular checks of the blood, heart, and blood pressure while taking ADDERALL XR. Children should have their height and weight checked often while taking ADDERALL XR. ADDERALL XR treatment may be stopped if a problem is found during these check-ups.
- **If you or your child takes too much ADDERALL XR or overdoses, call your doctor or poison control center right away, or get emergency treatment.**

What are possible side effects of ADDERALL XR?

See "**What is the most important information I should know about ADDERALL XR?**" for information on reported heart and mental problems.

Other serious side effects include:

- slowing of growth (height and weight) in children
- seizures, mainly in patients with a history of seizures
- eyesight changes or blurred vision

Common side effects include:

- headache
- decreased appetite
- stomach ache
- nervousness

- trouble sleeping
- mood swings
- weight loss
- dizziness
- dry mouth
- fast heart beat

ADDERALL XR may affect you or your child's ability to drive or do other dangerous activities.

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 .

How should I store ADDERALL XR?

- Store ADDERALL XR in a safe place at room temperature, 59 to 86° F (15 to 30° C).
- **Keep ADDERALL XR and all medicines out of the reach of children.**

General information about ADDERALL XR

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use ADDERALL XR for a condition for which it was not prescribed. Do not give ADDERALL 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 ADDERALL XR. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about ADDERALL XR that was written for healthcare professionals. For more information, you may also contact Shire Pharmaceuticals (the maker of ADDERALL XR) at 1-800-828-2088  or visit the website at <http://www.adderallxr.com>.

What are the ingredients in ADDERALL XR?

Active Ingredients: dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, USP, amphetamine sulfate USP

Inactive Ingredients: gelatin capsules, hydroxypropyl methylcellulose, methacrylic acid copolymer, opadry beige, sugar spheres, talc, and triethyl citrate. Gelatin capsules contain edible inks, kosher gelatin, and titanium dioxide. The 5 mg, 10 mg, and 15 mg capsules also contain FD&C Blue #2. The 20 mg, 25 mg, and 30 mg capsules also contain red iron oxide and yellow iron oxide

Manufactured for Shire US Inc., 300 Shire Way,
Lexington, MA 02421.

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