

INFORMATION FOR THE CONSUMER

ADDERALL XR®*

mixed salts amphetamine
extended-release capsules
5mg, 10mg, 15mg, 20mg, 25mg and 30mg

INFORMATION FOR PATIENTS TAKING ADDERALL XR OR FOR THEIR PARENT OR CAREGIVER

Please read this before you start taking / giving ADDERALL XR. It may answer some of the questions you have and help you to understand how to take/give ADDERALL XR to obtain the best results. However, this leaflet does not contain all available information about ADDERALL XR and does not take the place of your / your child's doctor's instructions. If you need more information or advice about ADDERALL XR, talk to your / your child's doctor or pharmacist.

The following have been reported with use of ADDERALL XR and other sympathomimetic medicines.

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 may wish to check you or your child carefully for heart problems before starting ADDERALL XR. Your doctor may wish to 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.

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 Adolescents

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

What is ADDERALL XR?

ADDERALL XR is a once-a-day treatment for Attention Deficit Hyperactivity Disorder (ADHD). ADDERALL XR capsules contain a combination of amphetamines, the active ingredient in the treatment of ADHD.

What is Attention Deficit Hyperactivity Disorder?

ADHD has three main types of symptoms: inattention, hyperactivity and impulsiveness. Symptoms of inattention include not paying attention, making careless mistakes, not listening, not finishing tasks, not organized, losing things, forgetful, not following directions and being easily distracted. Symptoms of hyperactivity and impulsiveness include fidgeting, talking excessively, running around at inappropriate times and interrupting others. Some patients have more symptoms of hyperactivity and impulsiveness while others have more symptoms of inattentiveness. Some patients have all three types of symptoms. Many people have symptoms like these from time to time, but patients with ADHD have these symptoms more than others their age. Symptoms must be present for at least six months to be certain of the diagnosis.

How does ADDERALL XR work?

Amphetamines, the active ingredient in ADDERALL XR, help increase attention (including the ability to follow directions and finish tasks) and decrease impulsiveness and hyperactivity in patients with ADHD. The ADDERALL XR capsule contains some beads that release medication immediately giving you / your child an initial dose of medication, and other delayed-release beads which release medication later during the day to keep improving the symptoms of ADHD throughout the day and into the early evening.

When ADDERALL XR should not be used

You / your child should NOT take ADDERALL XR if one or more of the following applies to you / your child:

- allergies to amphetamines or any of the other ingredients in ADDERALL XR
- advanced arteriosclerosis (hardened arteries)
- symptomatic cardiovascular disease
- moderate to severe high blood pressure
- agitated states
- glaucoma, an eye disease
- hyperthyroidism (an overactive thyroid gland)
- history of drug abuse
- has taken medications from the group called monoamine oxidase inhibitors (MAOI) within the last 14 days.

Before using ADDERALL XR

Use of ADDERALL XR may be unsuitable or require special attention under certain medical conditions. Tell the doctor if one or more of the following applies to you/ your child:

- heart disease or condition structural heart abnormalities, or high blood pressure
- family history of sudden death or death related to heart problems
- does strenuous exercise
- takes other drugs for ADHD
- has abnormal thoughts or visions, hears abnormal sounds or voices, or has been diagnosed with psychosis presently or in the past
- has symptoms of depression (feelings of sadness, worthlessness or hopelessness) or bipolar disorder (mood swings), or has been diagnosed with depression or bipolar disorder presently or in the past
- family history of suicide, depression, or bipolar disorder
- has motion tics (hard to control, repeat twitching of any parts of the body) or verbal tics (hard to control repeating of sounds or words) or Tourette's syndrome
- has relatives with motion tics, verbal tics, or Tourette's syndrome
- pregnancy or plans to become pregnant
- breastfeeding or plans to breastfeed
- has a history of seizures (convulsions, epilepsy)

Tell the doctor if you / your child develops any of the above conditions or symptoms while taking ADDERALL XR.

How should ADDERALL XR be taken?

ADDERALL XR should be taken by mouth, once a day early in the morning.

Capsules may be swallowed whole with water or milk. Capsules may be opened and all the beads inside sprinkled on applesauce and taken immediately; do not store for later use. **Do not crush or chew the capsule or the beads before swallowing.** ADDERALL XR can be taken with or without meals.

Do not take antacids at the same time as ADDERALL XR.

ADDERALL XR may interact with a class of medications that reduce the acid produced in the stomach called Proton Pump Inhibitors, commonly known as PPI (e.g., Losec®).

In order to receive the most benefit from ADDERALL XR, it is important that ADDERALL XR be taken only as directed by your / your child's doctor. The doctor may adjust the amount of drug taken by you / your child until it is right for you / your child. From time to time, the doctor may interrupt treatment to check your / your child's symptoms while you / your child is not taking the drug.

What are the possible side effects of ADDERALL XR?

Along with its desired effects, a medicine may cause some unwanted effects. Although not all of these side effects may occur, if they do occur, talk to your / your child's doctor.

During clinical studies with ADDERALL XR, the most common side effects in children aged 6 to 12 years were decreased appetite, stomach ache, difficulty falling asleep and mood swings; in adolescents aged 13 to 17 years were stomach ache, loss of appetite, difficulty falling asleep and weight loss; and in adults were dry mouth, decreased appetite, headache, difficulty falling asleep, and weight loss. This is not a complete list of possible side effects. Ask your / your child's doctor about other possible side effects.

Can ADDERALL XR be taken with other medications?

It is important to tell your / your child's doctor or pharmacist about all medicines that you / your child is taking including other medicines that a doctor has prescribed, medicines that you buy yourself without a prescription, and any herbal remedies that you / your child is taking.

Do not take antacids at the same time as ADDERALL XR.

ADDERALL XR may interact with a class of medications that reduce the acid produced in the stomach called Proton Pump Inhibitors, commonly known as PPI (e.g., Losec®).

While on ADDERALL XR, do not start taking a new medicine or herbal remedy before checking with the doctor.

Other important safety information:

Abuse of amphetamines can lead to dependence and possibly serious heart problems and death. Substance abuse may be less likely in patients with ADHD if they are treated with medication. ADDERALL XR should only be given under close medical supervision to patients whose condition has been properly diagnosed.

Sudden death has been reported with drugs used for ADHD treatment in children/adolescents with structural heart abnormalities or other serious heart problems. Although some serious heart problems alone can carry an increased risk of sudden death, ADDERALL XR generally should not be used in children, adolescents or adults with known structural heart abnormalities, disease of the heart muscle, serious heart rhythm abnormalities or other serious heart disease or conditions.

Other stimulants have been reported to temporarily slow growth in children, however there is not sufficient evidence to determine if ADDERALL XR in children may cause slower growth (slowed weight gain and/or height). The doctor will be carefully watching your / your child's height and weight. If you / your child is not growing or gaining weight as the doctor expects, the doctor may stop the patient's ADDERALL XR treatment.

Call the doctor **immediately** if you / your child takes more than the amount of ADDERALL XR prescribed by the doctor.

What else should I know about ADDERALL XR?

ADDERALL XR has not been studied in children under six years of age. ADDERALL XR has not been studied in pregnant women.

ADDERALL XR may be a part of the patient's overall treatment for ADHD. The doctor may also recommend that you / your child have counseling or other therapy.

As with all medicines, never share ADDERALL XR with anyone else and take only the number of ADDERALL XR capsules prescribed by your / your child's doctor.

Storage**Keep out of the reach of children.**

Store ADDERALL XR at 25°C (excursions permitted to 15 -30°C) in a tight, light-resistant container.

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