

PART III: CONSUMER INFORMATION

ADDERALL XR®*
 mixed salts amphetamine
 extended-release capsules

Read this carefully before you start taking ADDERALL XR. This leaflet is a summary and will not tell you everything about ADDERALL XR. Contact your doctor, nurse or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION**What the medication is used for:**

ADDERALL XR is used for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in children (6-12 years), adolescents (13-17 years) and adults.

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

What it does:

Mixed salts amphetamine, the medicinal 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 it should not be used:

Do not take ADDERALL XR if you/your child:

- Are allergic to amphetamines or any of the nonmedicinal ingredients in the formulation or its container (see What the nonmedicinal ingredients are)
- Are sensitive to, allergic to or had a reaction to other stimulant medicines
- Have advanced arteriosclerosis (hardened arteries)
- Have symptomatic heart disease
- Have moderate to severe high blood pressure
- Have agitated states
- Have glaucoma, an eye disease
- Have hyperthyroidism (an overactive thyroid gland)
- Have history of drug abuse
- Are taking or have taken medications from the group called monoamine oxidase inhibitors (MAOI) within the last 14 days.
- Are breastfeeding or plan to breastfeed. ADDERALL XR passes into breast milk.

What the medicinal ingredient is:

Mixed salts amphetamine: *d*-amphetamine Saccharate, Amphetamine Aspartate Monohydrate, *d*-amphetamine Sulfate and Amphetamine Sulfate

What the nonmedicinal ingredients are:

Edible inks, FD&C Blue #2 (5mg, 10mg and 15mg capsules), hydroxypropyl methylcellulose, kosher gelatin, methacrylic acid copolymer, opadry beige, red iron oxide (20mg, 25mg and 30mg capsules), starch, sugar spheres, talc, titanium dioxide, triethyl citrate, yellow iron oxide (20mg, 25mg and 30mg capsules).

What dosage forms it comes in:

Extended-release capsules: 5mg, 10mg, 15mg, 20mg, 25mg and 30mg

WARNINGS AND PRECAUTIONS**Serious Warnings and Precautions**

ADDERALL XR has a potential for abuse, misuse and dependence.

The misuse of ADDERALL XR may cause serious cardiovascular adverse events and sudden death.

(See also **Drug Abuse and Dependence** below)

The following have been reported with use of medicines used to treat ADHD such as ADDERALL XR:

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**

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.

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.

2. Mental (Psychiatric) problems:

- **New or worse thoughts or feelings related to suicide (thinking about or feeling like killing yourself) and suicide actions (suicide attempt, completed suicide)**
- **New or worse bipolar illness, characterized by extreme mood swings, with periods of mania (unusually excited, over-active or un-inhibited) alternating with periods of**

depression (feelings of sadness, worthlessness or hopelessness)

- **New or worse aggressive behavior or hostility**
- **New psychosis (such as hearing voices, believing things that are not true, are suspicious) or new mania (unusually excited, over-active or un-inhibited)**

These new or worse mental problems may be more likely to occur if you/your child have mental disorders that you may or may not know about. Tell your doctor about any mental problems you or your child have, or about any personal or family history of suicide, bipolar illness, or depression.

A small number of patients taking ADHD drugs may experience unusual feelings of agitation, hostility or anxiety, or have impulsive or disturbing thoughts such as thoughts of suicide, self-harm or harm to others. Those suicidal thoughts or behaviors may occur at any time *during* treatment, particularly at the start or during dose changes, and also *after stopping* ADDERALL XR. **Should this happen to you, or to those in your care if you are a caregiver or guardian, talk to your doctor immediately. Close observation by a doctor is necessary in this situation.**

Call your doctor right away if you or your child has 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.

BEFORE you/your child uses ADDERALL XR, talk to your doctor, nurse, or pharmacist if you/your child:

- have heart disease or a heart condition, structural heart abnormalities or high blood pressure
- have a family history of sudden death or death related to heart problems
- participate in strenuous exercise or activities
- take other drugs for ADHD
- have mental problems or a family history of mental problems including psychosis, mania, bipolar illness, depression or suicide.
- have 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
- have relatives with motion tics, verbal tics, or Tourette's syndrome
- have a history of seizures (convulsions, epilepsy) or have had an abnormal brain wave test (EEG)
- are pregnant or plan to become pregnant. Taking ADDERALL XR during pregnancy can cause harm to your baby. If ADDERALL XR is required during pregnancy, the risk to the unborn baby should be weighed against the benefits for the mother. Your doctor can discuss these issues with you
- have symptoms of Raynaud's phenomenon (fingers and toes feeling numb, tingling and changing colour when cold) or thromboangitis obliterans (causes pain in hands and feet)
- have any kidney related problems as your doctor may reduce the dose.

Drug Abuse and Dependence

Amphetamines have the potential for abuse and misuse. 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 (see Serious Warnings and Precautions above).

Growth in Children

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 ADDERALL XR treatment.

INTERACTIONS WITH THIS MEDICATION

As with most medicines, interactions with other drugs are possible. Tell your doctor, nurse, or pharmacist about all the medicines you/your child takes, including drugs prescribed by other doctors, vitamins, minerals, natural or herbal supplements, or alternative medicines.

The following may interact with ADDERALL XR:

- medicines used to treat depression including monoamine oxidase inhibitors (MAOIs), selective serotonin reuptake inhibitors (SSRIs) and serotonin and noradrenaline reuptake inhibitors (SNRIs)
- medicines that make urine or digestive contents more acidic (e.g., guanethidine, reserpine, ascorbic acid, ammonium chloride, sodium acid phosphate)
- medicines that make urine or digestive contents more alkaline (e.g., sodium bicarbonate, acetazolamide, thiazides)
- medicines used to reduce or increase blood pressure
- cold and allergy medicines
- antipsychotic medicines (e.g., chlorpromazine, haloperidol)
- lithium
- methenamine therapy
- narcotic pain medicines (e.g., meperidine)
- seizure medicines (e.g., ethosuximide, phenobarbital, phenytoin)
- antacids, 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., omeprazole). Therefore, do not take antacids at the same time as ADDERALL XR.

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

PROPER USE OF THIS MEDICATION

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.

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.

Your doctor may do regular checks of the 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.

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.

Usual dose:

Children (6 to 12 years of age): The usual starting dose is 10mg once a day in the morning. The dose may be adjusted up to a maximum dose of 30mg/day.

Adolescents (13 to 17 years of age) and Adults (18 years of age and over): The usual starting dose is 10mg once a day in the morning. The dose may be adjusted up to the usual maximum dose of 20mg/day. In some cases a maximum daily dose of 30mg/day may be used.

Overdose:

If you think you/your child has taken too much ADDERALL XR contact your doctor, nurse, pharmacist, hospital emergency department or regional Poison control Centre immediately, even if there are no symptoms.

Missed Dose:

If you/your child forget to take your/his or her dose in the morning, wait until the next morning and carry on with the next dose at the usual time. Do not double dose.

Afternoon doses should be avoided because of the long-acting nature of the drug, including the potential for insomnia.

- dry mouth
- headache
- dizziness
- nervousness, anxiety, irritability
- vomiting, nausea, diarrhea

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor, nurse, or pharmacist		Stop taking drug and seek immediate medical help
		Only if severe	In all cases	
Common	Heart palpitations or fast heart beat (see Warnings and Precautions)		√	
	Allergic Reaction: rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			√
	New Tics		√	
	Depression: feeling sad, loss of interest in usual activities, hopelessness, insomnia or sleeping too much		√	
Uncommon	Aggressive Behavior, Anger or Hostility		√	
	High Blood Pressure: headaches, dizziness, lightheadedness, ringing in the ears, fainting		√	
	Trouble with vision: eyesight changes or blurred vision		√	
Unknown	Heart attack: severe, crushing chest pain that can radiate into the arm and/or jaw, palpitations, shortness of breath, nausea, vomiting, sweating (see Warnings and Precautions)			√

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects may include:

- decrease or loss of appetite
- stomach ache
- difficulty falling asleep
- mood swings
- weight loss

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor, nurse, or pharmacist		Stop taking drug and seek immediate medical help
		Only if severe	In all cases	
Unknown	New Psychotic or Manic Symptoms: Paranoia, delusions -Hallucinations: Seeing, feeling or hearing things that are not real, -Mania: feeling unusually excited, over-active, or uninhibited (see Warnings and Precautions)		√	
	Suicidal Behavior: Thoughts or actions about hurting or killing yourself (see Warnings and Precautions)			√
	Fits (seizures)			√
	Condition Resembling Raynaud's Phenomenon: discoloration of the hands and feet, pain, sensations of cold and/or numbness		√	
	Stroke: weakness, trouble speaking, vision problems, headache, dizziness			√
	Serious Skin Conditions (Steven's Johnson Syndrome, Toxic Epidermal Necrolysis): Swelling of the skin or serious skin rash seen as severe blisters of the skin and mucous membranes			√

This is not a complete list of side effects. For any unexpected effects while taking ADDERALL XR, contact your doctor, nurse or pharmacist.

HOW TO STORE IT

Keep out of the reach and sight of children.

Store at room temperature (15-30°C) in a tight, light-resistant container.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701E
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

If you want more information about ADDERALL XR:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Consumer Information by visiting the Health Canada website <http://hc-sc.gc.ca>, the manufacturer's website www.shirecanada.com, or by calling 1-800-268-2772.

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