



## Patient Information Sheet

# Adderall and Adderall XR Extended-Release Capsules

This is a summary of the most important information about Adderall and Adderall XR. For details, talk to your healthcare professional.

### **FDA ALERT [08/05] Health Canada Announces Return of Adderall to the Canadian Market.**

Adderall will return to the Canadian market for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) (see alert of 02/09/05 below). The Canadian Product Monograph will be revised to include warnings about the misuse of Adderall and that Adderall generally should not be used in patients with structural cardiac abnormalities.

### **FDA Alert [02/05] Health Canada Suspends Marketing of Adderall**

Health Canada has suspended marketing of Adderall products from the Canadian market due to concern about reports of sudden unexplained death (SUD) in children taking Adderall. SUD has been associated with amphetamine abuse and reported in children with underlying cardiac abnormalities taking recommended doses of amphetamines, including Adderall. In addition, a very small number of cases of SUD have been reported in children without structural cardiac abnormalities taking Adderall. At this time, FDA cannot conclude that recommended doses of Adderall can cause SUD, but is continuing to carefully evaluate these data.

Adderall labeling contains a serious warning about the potential for abuse.

#### **WARNING: ABUSE POTENTIAL**

Amphetamines have a high potential for abuse. Taking amphetamines for long periods of time may lead to drug addiction. Particular attention should be paid to the possibility of people obtaining amphetamines for non-therapeutic use or distribution to others.

Misuse of amphetamine may cause sudden death and serious cardiovascular adverse events.

### **What Is Adderall XR?**

Adderall is a central nervous system stimulant (amphetamine). Adderall is used to treat attention deficit hyperactivity disorder (ADHD) in children 6 years of age and older and in adults.

### **Who Should Not Take Adderall ?**

You should not take Adderall if you have:

- A heart defect
- Other heart problems, including high blood pressure, and heart or blood vessel disease

- Overactive thyroid
- Glaucoma
- A history of drug abuse

Never take Adderall if you are taking a drug used to treat depression, called a Monoamine Oxidase Inhibitor (MAOI), or if you have stopped taking an MAOI in the last 14 days. Taking Adderall close in time to an MAOI can result in serious, sometimes fatal, reactions, including:

- High body temperature
- Coma
- Seizures (convulsions)

MAOI drugs include Nardil (phenelzine sulfate), Parnate (tranylcypromine sulfate), Marplan (isocarboxid), and other brands.

### **What Are The Risks?**

- **Sudden deaths:** See FDA Alert.
- **Abuse potential:** See Warning.
- **Worsening mental illness (psychosis):** Adderall may make symptoms of existing mental illness worse.
- **Possible decreased growth and weight loss:** Adderall may decrease growth and cause weight loss. Children who take it for a long time should have their growth and body weight measured regularly.
- **Increased tics:** Adderall may worsen tics and Tourette's disorder.
- **Pregnancy:** Tell your healthcare professional if you are or may be pregnant because your baby may be premature or have a low birth weight. Also, your baby may show withdrawal symptoms, such as agitation and drowsiness.
- **Breast feeding:** Do not breast feed while taking Adderall because it can pass into your breast milk.
- **Other side effects** include loss of appetite, difficulty sleeping, dry mouth, headaches, and mood changes.
- **Tell your healthcare professional** about any medical conditions you have in addition to those already mentioned in this information sheet.

### **Are There Any Interactions With Drugs or Foods?**

- Adderall may interact with other medicines. These interactions can cause serious side effects. Tell your healthcare professional about all medicines, vitamins, and herbal supplements you take, especially:
  - Those used to treat depression, known as tricyclic antidepressants and monoamine oxidase inhibitors (MAOI)
  - Antacids
  - Those used to treat urinary tract problems
  - Diuretics
  - Propoxyphene (Darvon, Darvocet), a pain medicine





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#### How Do I Take Adderall ?

- Adderall is taken by mouth, in the morning, with or without food, exactly as prescribed by your healthcare professional.
- Swallow Adderall capsules whole or open the capsule and sprinkle the contents on a spoonful of applesauce. Take right away without chewing.

**Adderall XR FDA Approved 2001  
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