WARNING: Abuse and Dependence

Data from postmarketing surveillance indicate abuse of amphetamine products is a problem. Federal and local law prohibit the illegal use of these drugs. Abuse of these drugs, when taken for non-prescribed indications, may result in serious and life-threatening adverse reactions (see Warnings and Precautions [5.1] and Drug Abuse and Dependence [6.2]). Amphetamines, when misused, may result in serious and life-threatening adverse reactions. Patients should be informed that amphetamines may pose a risk of overdose and misuse (see Warnings and Precautions [5.1] and Drug Abuse and Dependence [6.2]).

Precaution: Prior to initiating treatment with Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, amphetamine sulfate extended-release, the physician who elects to use these drugs for a patient is responsible for ensuring that treatment will not be misused or diverted. To help prevent misuse or diversion, practitioner must implement procedures to ensure proper use of the product, including the use of appropriate safeguards to prevent the loss or theft of uncontrolled substances (see Warnings and Precautions [5.1] and Drug Abuse and Dependence [6.2]).

In adults the use of CNS stimulants, such as amphetamines, are associated with a risk of serious adverse events with a proactive potential for misused. Appropriate educational placement is essential and psychosocial intervention is often helpful. When remedial educational strategies are not sufficient to manage hyperactive/impulsive behavior, amphetamine products may be helpful (see Warnings and Precautions [5.1] and Drug Abuse and Dependence [6.2]).

In adult patients with severe renal impairment (GFR 15 to < 30 mL/min/1.73 m²), the recommended dose is 15 mg once daily in the morning. In pediatric patients with severe renal impairment (GFR 15 to < 30 mL/min/1.73 m²), the recommended dose is 5 mg once daily. When using other medications with amphetamines, it is important to consider the relative risk of multiple medications and other factors that may impact on the safe use of these medications (see Warnings and Precautions [5.1] and Drug Abuse and Dependence [6.2]).

ADVERSE REACTIONS

The most common adverse reactions associated with amphetamines are increased alertness, increased blood pressure, increased heart rate, and increased body temperature. Adverse reactions associated with the use of amphetamines also include insomnia, headache, nervousness, irritability, and tachycardia. These adverse reactions may be more pronounced in children and adolescents compared to adults. Adverse reactions associated with the use of amphetamines also include constipation, anorexia, and decrease in appetite. When used in conjunction with other medications, these adverse reactions may be more pronounced (see Warnings and Precautions [5.1] and Drug Abuse and Dependence [6.2]).

ADVERSE REACTIONS Leading to Discontinuation of Treatment

Approximately 8% of patients treated with Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, amphetamine sulfate extended-release in the treatment of ADHD experienced adverse reactions that led to discontinuation of treatment (see Warnings and Precautions [5.1] and Drug Abuse and Dependence [6.2]).

PREGNANCY

Pregnant and nursing mothers should be advised to consult a physician before taking Amphetamines. The use of Amphetamines during pregnancy is associated with maternal and fetal risks including maternal hypertension and preterm labor (see Warnings and Precautions [5.1] and Drug Abuse and Dependence [6.2]).

FETAL OR NEONATAL EFFECTS

There is a potential for neonatal withdrawal syndrome in infants born to mothers taking amphetamines during pregnancy. (see Warnings and Precautions [5.1] and Drug Abuse and Dependence [6.2]).

PREGNANCY REGISTRY

Pregnancy Registry for Psychostimulants at 1-866-961-2388 or visiting online at https://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/

FERTILITY

Men taking amphetamines for extended periods of time may experience temporary oligospermia. (see Warnings and Precautions [5.1] and Drug Abuse and Dependence [6.2]).

NURSE EXPOSURE

The risk of irregular menstruation and ovulation during pregnancy has not been established (see Warnings and Precautions [5.1] and Drug Abuse and Dependence [6.2]).

LACTATION

There is no information from human or animal studies on the transfer of amphetamines into milk. Long-term or neurodevelopmental effects of amphetamines on infants exposed to amphetamines while breastfeeding are not established (see Warnings and Precautions [5.1] and Drug Abuse and Dependence [6.2]).

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Amphetamine, in the enantiomer ratio present in Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, amphetamine sulfate extended-release.

What is the most important information I should know about Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, amphetamine sulfate extended-release?

You should not take d,l-Amphetamine (1:1 enantiomer ratio) has been reported to produce a positive response in the mouse bone marrow micronucleus test, an equivocal response in the Ames test, and negative responses in the Salmonella typhimurium mutagenesis test.

Physical Dependence (which is manifested by a withdrawal syndrome produced by abrupt cessation, rapid dose reduction, or administration of an antagonist) may occur. Tolerance (a state of adaptation in which exposure to a specific dose of a drug results in a reduction of the drug's desired and/or undesired effects over time, in such a way that increasing doses are needed to produce the original effects) may also develop.

Dialysis did not significantly affect the clearance of d,l-Amphetamine (1:1 enantiomer ratio) in adults and children. The effects of hemodialysis on the clearance and plasma concentration of d,l-Amphetamine (1:1 enantiomer ratio) in patients with severe renal impairment have not been studied.

Your doctor should check your or your child's blood pressure and heart rate regularly during treatment. Your doctor and pharmacist should teach you how to monitor your blood pressure at home and what your blood pressures should be. Keep a list of your blood pressures to show your doctor at your next checkup.

Tell your doctor or pharmacist if you are taking, have taken, or plan to take any of the following medicines or other products because of the risk of interactions:

- blood pressure medicines
- stomach acid medicines
- medicines for heartburn orGER (gastroesophageal reflux) disease
- medicines for irritable bowel syndrome
- medicines for diabetes
- medicines for seizures
- medicines for depression or other mental health disorders
- herbal medicines or dietary supplements such as guarana, ma huang (ephedra), or Siberian ginseng
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