

## **MEDICATION GUIDE**

### **DEXTROAMPHETAMINE SACCHARATE, AMPHETAMINE ASPARTATE MONOHYDRATE, DEXTROAMPHETAMINE SULFATE AND AMPHETAMINE SULFATE EXTENDED-RELEASE CAPSULES**

**(DEX-troe-am-FET-uh-meen SACK-uh-rate, am-FET-uh-meen ass-PAR-tate, MAN-no-HIGH-drate, DEX-troe-am-FET-uh-meen SULL-fate, and am-FET-uh-meen SULL-fate),CII**

Read the Medication Guide that comes with dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules 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 dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules.

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

**Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules 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 dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules.

Your doctor should check you or your child's blood pressure and heart rate regularly during treatment with dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules.

**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 dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules.**

## **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 dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules, 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 dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules.**

## **What is dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules?**

Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules is a once daily central nervous system stimulant prescription medicine. **It is used for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).** Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules may help increase attention and decrease impulsiveness and hyperactivity in patients with ADHD.

Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules should be used as a part of a total treatment program for ADHD that may include counseling or other therapies.

**Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules is a federally controlled substance (CII) because it can be abused or lead to dependence. Keep dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules in a safe place to prevent misuse and abuse. Selling or giving away dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules 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 dextroamphetamine saccharate, amphetamine aspartate monohydrate,**

## **dextroamphetamine sulfate and amphetamine sulfate extended-release capsules?**

### **Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules 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

Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules has not been studied in children less than 6 years old.

### **Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules may not be right for you or your child. Before starting dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules tell you or your child's doctor about all health conditions (or a family history of) including if you or your child:**

- have heart problems, heart defects, or high blood pressure
- have mental problems including psychosis, mania, bipolar illness, or depression
- have tics or Tourette's syndrome
- have liver problems
- have kidney problems
- have end stage renal disease (ESRD)
- have thyroid problems
- have seizures or have had an abnormal brain wave test (EEG)
- have circulation problems in fingers and toes
- are pregnant or plan to become pregnant. It is not known if dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules will harm your unborn baby.
  - There is a pregnancy registry for females who are exposed to dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules during pregnancy. The purpose of the registry is to collect information about the health of females exposed to dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules and their baby. If you or your child becomes pregnant during treatment with dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules, talk to your healthcare provider about registering with the National Pregnancy Registry of Psychostimulants at 1-866-961-2388 or visit online at <https://womensmentalhealth.org/clinical-and-researchprograms/pregnancyregistry/othermedications/>.
  - are breastfeeding or plan to breastfeed. Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate passes into breast milk. You or your child should not breastfeed during treatment with dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules.

### **Can dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules 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.** Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules 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 dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules.

Your doctor will decide whether dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules can be taken with other medicines.

**Especially tell your doctor if you or your child takes:**

- anti-depression medicines including MAOIs
- anti-psychotic medicine
- lithium
- narcotic pain medicines
- cold or allergy medicines that contain decongestants
- seizure medicines
- blood thinner medicines
- blood pressure medicines
- stomach acid medicines

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 dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules without talking to your doctor first.**

**How should dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules be taken?**

- **Take dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules exactly as prescribed.** Your doctor may adjust the dose until it is right for you or your child.
- Take dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules once a day in the morning when you first wake up. Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules is an extended release capsule. It releases medicine into your body throughout the day.
- Swallow dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release 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.**
- Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules can be taken with or without food.
- From time to time, your doctor may stop dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules treatment for a while to check ADHD symptoms.
- Your doctor may do regular checks of the heart and blood pressure while taking dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules. Children should have their height and weight checked often while taking dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules. Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules treatment may be stopped if a problem is found during these check-ups.
- **If you or your child takes too much dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules or overdoses, call your doctor or poison control center right away, or get emergency treatment.**

## **What are possible side effects of dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules?**

See "**What is the most important information I should know about dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules?**" 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

Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules 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 dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules?**

- Store dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules in a safe place at room temperature, 59° to 86° F (15° to 30° C).
- **Keep dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules and all medicines out of the reach of children.**

## **General information about dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules for a condition for which it was not prescribed. Do not give dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules 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 dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules that was written for healthcare professionals. For more information, you may also contact Elite Laboratories, Inc. at 1-888-852-6657 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

## **What are the ingredients in dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules?**

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

**Inactive Ingredients:** ferric oxide red, ferric oxide yellow, gelatin capsules, hypromellose 2910/3 cP, 6 cP and 50 cP, methacrylic acid and ethyl acrylate copolymer, titanium dioxide, polyethylene glycol, polysorbate 80, sugar spheres, talc, and triethyl citrate.

The 5 mg gelatin capsules contain gelatin, titanium dioxide, D&C yellow #10, FD&C blue #1 and FD&C yellow #6.

The 10 mg gelatin capsules contain gelatin, FD&C blue #1, and FD&C red #40.

The 15 mg gelatin capsules contain gelatin, titanium dioxide, FD&C blue #1, and FD&C yellow #6.

The 20 mg gelatin capsules contain gelatin, titanium dioxide, and FD&C red #3.

The 25 mg gelatin capsules contain gelatin, FD&C red #40, and FD&C yellow #6.

The 30 mg gelatin capsules contain gelatin, titanium dioxide, D&C red #28, and FD&C red #40.

The ink ingredients are common for all strengths: the capsule imprint black ink contains FD&C blue #1 aluminum lake, FD&C red #40 aluminum lake, FD&C yellow #6 aluminum lake, propylene glycol, and shellac.

Manufactured for:

**Burel Pharmaceuticals, LLC**

Mason, OH 45040 USA

For more information call 1-888-852-6657

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

PI0022

Rev. 08/2023