

## 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), (mixed salts of single-entity amphetamine product) extended-release capsules, CII

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**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 may cause serious side effects, including:**

- **Abuse, misuse, and addiction.** Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules have a high chance for abuse and misuse and may lead to substance use problems, including addiction. Misuse and abuse of dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules, other amphetamines containing medicines, and methylphenidate containing medicines, can lead to overdose and death. The risk of overdose and death is increased with higher doses of dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules or when it is used in ways that are not approved, such as snorting or injection.
  - Your healthcare provider should check you or your child's risk for abuse, misuse, and addiction before starting treatment with dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules and will monitor you or your child during treatment.
  - Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules may lead to physical dependence after prolonged use, even if taken as directed by your healthcare provider.
  - Do not give dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules to anyone else. See **“What is Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules?”** for more information.
  - Keep dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules in a safe place and properly dispose of any unused medicine. See **“How should I store Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules?”** for more information.

Tell your healthcare provider if you or your child have ever abused or been dependent on alcohol, prescription medicines, or street drugs.

- **Risks for people with serious heart disease.** Sudden death has happened in people who have heart defects or other serious heart disease. Your healthcare provider should check you or your child carefully for heart problems before starting treatment with dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-

release capsules. Tell your healthcare provider if you or your child have any heart problems, heart disease, or heart defects.

**Call your healthcare provider or go to the nearest hospital emergency room right away if you or your child have any signs of heart problems such as chest pain, shortness of breath, or fainting during treatment with dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules.**

- **Increased blood pressure and heart rate.**

Your healthcare provider 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.

- **Mental (Psychiatric) problems, including:**

- new or worse behavior or thought problems
- new or worse bipolar illness
- new psychotic symptoms (such as hearing voices, or seeing or believing things that are not real) or new manic symptoms

Tell your healthcare provider about any mental problems you or your child have or about a family history of suicide, bipolar illness, or depression.

**Call your healthcare provider right away if you or your child have any new or worsening mental symptoms or problems during treatment with dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules, especially hearing voices, seeing or believing things that are not real, or new manic symptoms.**

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**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 central nervous system (CNS) stimulant prescription medicine used for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in adults and children 6 years of age and older. Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules may help increase attention and decrease impulsiveness and hyperactivity in people with ADHD.

It is not known if dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules are safe and effective in children under 6 years of age.

**Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules is a federally controlled substance (CII) because it contains amphetamine that can be a target for people who abuse prescription medicines or street drugs.**

Keep dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules in a safe place to protect it from theft. Never give your dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules to anyone else because it may cause death or harm them. 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.

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**Do not take dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules if you or your child:**

- are taking or have taken within the past 14 days, a medicine used to treat depression called a monoamine oxidase inhibitor (MAOI), including the antibiotic linezolid or the intravenous medicine methylene blue.
- are allergic to amphetamine products or any of the ingredients in dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules. See the end of this Medication Guide for a complete list of ingredients in dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules.

**Before taking dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules tell your healthcare provider about all of your or your child's medical conditions, including if you or your child:**

- have heart problems, heart disease, heart defects, or high blood pressure
- have mental problems including psychosis, mania, bipolar illness, or depression, or

- have a family history of suicide, bipolar illness, or depression
- have kidney problems
- have seizures or have had an abnormal brain wave test (EEG)
- have circulation problems in fingers and toes
- have or had repeated movements or sounds (tics) or Tourette's syndrome, or have a family history of tics or Tourette's syndrome
- 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. Tell your healthcare provider if you or your child become pregnant during treatment with dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules.
  - 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 extended-release capsules pass 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. Talk to your healthcare provider about the best way to feed the baby during treatment with dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules.

**Tell your healthcare provider about all of the medicines that you or your child take,** including prescription and over-the-counter 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 changed during treatment with dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules.

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

**Especially tell your healthcare provider if you or your child take:**

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| • selective serotonin reuptake inhibitors (SSRIs)             | • tramadol   | • tricyclic antidepressants |
| • medicines used to treat migraine headaches called triptans. | • buspirone  | • fentanyl                  |
| • lithium   | • serotonin norepinephrine reuptake inhibitors (SNRIs) | • tryptophan                |
|   |  | • St. John's Wort           |
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Know the medicines that you or your child take. Keep a list of your or your child's medicines with you to show your healthcare provider and pharmacist when you or your child get a new medicine.

**Do not start any new medicine during treatment with dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules without talking to your healthcare provider 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 by your or your child's healthcare provider.
- Your healthcare provider may change the dose if needed.
- Take dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules 1

time each day in the morning when you first wake up.

- Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules can be taken with or without food.
- Swallow dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules whole. If you or your child cannot swallow the capsule whole, open it and sprinkle the medicine on applesauce.
  - Swallow all of the applesauce and medicine right away.
  - **Do not** chew the applesauce and medicine mixture.
  - **Do not** store the applesauce sprinkled with dextroamphetamine sulfate and amphetamine sulfate extended-release capsules.

If you or your child take too much dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules call your healthcare provider or Poison Help Line at 1-800-222-1222 or go to the nearest hospital emergency room right away.

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### **What are possible side effects of 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 may cause serious side effects, including:**

- **See "What is the most important information I should know about dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules?"**
- **Slowing of growth (height and weight) in children.** Children should have their height and weight checked often during treatment with dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules. Your healthcare provider may stop your child's dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules treatment if they are not growing or gaining weight as expected.
- **Seizures.** Your healthcare provider may stop treatment with dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules if you or your child have a seizure.
- **Circulation problems in fingers and toes (Peripheral vasculopathy, including Raynaud's phenomenon).**

Signs and symptoms may include:

- fingers or toes may feel numb, cool, painful
- fingers or toes may change color from pale, to blue, to red

Tell your healthcare provider if you or your child have numbness, pain, skin color change, or sensitivity to temperature in your fingers or toes.

#### **Call your healthcare provider right away if you or your child have any signs of unexplained wounds appearing on fingers or toes during treatment with dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules.**

- **Serotonin syndrome.** This problem may happen when dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules are taken with certain other medicines and may be life-threatening. Stop taking dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules and call your healthcare provider or go to the nearest hospital emergency room right away if you or your child develop any of the following signs and symptoms of serotonin syndrome:

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| • agitation, hallucinations, coma, or other changes in mental status | • dizziness                            |
| • problems controlling movements or muscle twitching                 | • change in blood pressure             |
| • fast heartbeat   | • sweating or fever                    |
| • seizures   | • nausea, vomiting, diarrhea           |
| • loss of coordination   | • muscle stiffness or tightness        |
| • confusion  | • high body temperature (hyperthermia) |
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- **New or worsening tics or worsening Tourette's Syndrome.** Tell your healthcare provider if you or your child get any new or worsening tics or worsening Tourette's syndrome during treatment with dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules.

**The most common side effects of dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules in children ages 6 to 12 include:**

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| • loss of appetite         | • mood swings | • nausea |
| • trouble sleeping         | • vomiting    | • fever  |
| • stomach (abdominal) pain | • nervousness |          |
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**The most common side effects of dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules in adolescents ages 13 to 17 include:**

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| • loss of appetite         | • weight loss |
| • trouble sleeping         | • nervousness |
| • stomach (abdominal pain) |               |
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**The most common side effects of dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules in adults include:**

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| • dry mouth        | • nausea         | • diarrhea                        |
| • loss of appetite | • anxiety        | • weakness                        |
| • trouble sleeping | • agitation      | • urinary tract infections (UTIs) |
| • headache         | • dizziness      |                                   |
| • weight loss      | • fast heartbeat |                                   |
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These are not all possible side effects of dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

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**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 at room temperature between 68 to 77°F (20 to 25°C).
- Protect dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules from light.
- Store dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules in a safe place, like a locked cabinet.
- Dispose of remaining, unused, or expired dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules by a medicine take-back program at a U.S. Drug Enforcement Administration (DEA) authorized collection site. If no take-back program or DEA authorized collector is available, mix dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules with an undesirable, nontoxic substance such as dirt, cat litter, or used coffee grounds to make it less appealing to children and pets. Place the mixture in a container such as a sealed plastic bag and throw away dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules in the household trash. Visit [www.fda.gov/drugdisposal](http://www.fda.gov/drugdisposal) for additional information on disposal of unused medicines.

**Keep dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules and all medicines out of the reach of children.**

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**General information about the safe and effective use of 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.

You can ask your healthcare provider or pharmacist for information about dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules that is written for healthcare professionals.

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

**Active Ingredient:** dextroamphetamine sulfate, amphetamine sulfate, dextroamphetamine saccharate, and amphetamine aspartate monohydrate

**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**

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For more information call 1-888-852-6657

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

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