

MEDICATION GUIDE DEXTROAMPHETAMINE SACCHARATE, AMPHETAMINE ASPARTATE MONOHYDRATE, DEXTROAMPHETAMINE SULFATE, AMPHETAMINE SULFATE (Mixed Salts of a Single-Entity Amphetamine Product) EXTENDED-RELEASE CAPSULES, CII (dex'' troe am fet' a meen sak'' a rate), (am fet' a meen a spar'' tate mon'' oh hye' drate), (dex'' troe am fet' a meen sul' fate), (am fet' a meen sul' fate)
<p>What is the most important information I should know about dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, amphetamine sulfate extended-release capsules?</p> <p>Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, amphetamine sulfate extended-release capsules may cause serious side effects, including:</p> <ul style="list-style-type: none"> • Abuse, misuse, and addiction. Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, amphetamine sulfate extended-release capsules has 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, amphetamine sulfate extended-release capsules, other amphetamine 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, amphetamine sulfate extended-release capsules or when it is used in ways that are not approved, such as snorting or injection. <ul style="list-style-type: none"> ○ 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, amphetamine sulfate extended-release capsules and will monitor you or your child during treatment. ○ Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, 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, amphetamine sulfate extended-release capsules to anyone else. See “What are dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, amphetamine sulfate extended-release capsules?” for more information. ○ Keep dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, 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, amphetamine sulfate extended-release capsules?” for more information. <p>Tell your healthcare provider if you or your child have ever abused or been dependent on alcohol, prescription medicines or street drugs.</p> <ul style="list-style-type: none"> • Risks for people with serious heart disease. Sudden death has happened in people who have heart defects or other serious heart disease. <p>Your healthcare provider should check you or your child carefully for heart problems before starting dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, amphetamine sulfate extended-release capsules. Tell your healthcare provider if you or your child have any heart problems, heart disease, heart defects.</p> <p>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, amphetamine sulfate extended-release capsules.</p> <ul style="list-style-type: none"> • Increased blood pressure and heart rate. <p>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, amphetamine sulfate extended-release capsules.</p> <ul style="list-style-type: none"> • Mental (psychiatric) problems, including: <ul style="list-style-type: none"> ○ new or worse behavior and 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 <p>Tell your healthcare provider about any mental problems you or your child have, or about a family history of suicide, bipolar illness, or depression.</p> <p>Call your healthcare provider 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, amphetamine sulfate extended-release capsules, especially hearing voices, seeing or believing things that are not real, or new manic symptoms.</p> <p>What are dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, amphetamine sulfate extended-release capsules?</p> <p>Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, amphetamine sulfate extended-release capsules are a central nervous system (CNS) stimulant prescription medicine used for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in people 13 years of age and older.</p>

<p>Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, amphetamine sulfate extended-release capsules are not for use in children 12 years of age and younger.</p> <p>Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, amphetamine sulfate extended-release capsules are 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, amphetamine sulfate extended-release capsules in a safe place to protect it from theft. Never give your dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, 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, amphetamine sulfate extended-release capsules may harm others and is against the law.</p> <p>Do not take dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, amphetamine sulfate extended-release capsules if you or your child are:</p> <ul style="list-style-type: none"> • allergic to amphetamine or any of the ingredients in dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, amphetamine sulfate extended-release capsules. See the end of the Medication Guide for a complete list of ingredients in dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, amphetamine sulfate extended-release capsules. • taking, or have taken within the past 14 days, a medicine used to treat depression called a monoamine oxidase inhibitor (MAOI). <p>Before taking dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, amphetamine sulfate extended-release capsules, tell your healthcare provider about all medical conditions, including if you or your child:</p> <ul style="list-style-type: none"> • 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 circulation problems in fingers and toes • have or have had seizures • have kidney problems • 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, amphetamine sulfate extended-release capsules will harm your unborn baby. Tell your healthcare provider if you become pregnant during treatment with dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, amphetamine sulfate extended-release capsules. <ul style="list-style-type: none"> ○ There is a pregnancy registry for females who are exposed to dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, 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, 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, amphetamine sulfate extended-release capsules, talk to your healthcare provider about registering with the National Pregnancy Registry for Psychiatric Medications at 1-866-961-2388 or visit online at https://womensmentalhealth.org/research/pregnancyregistry/. • are breastfeeding or plan to breastfeed. Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate pass into breast milk. You should not breastfeed during treatment with dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, amphetamine sulfate extended-release capsules. <p>Tell your healthcare provider about all the medicines that you or your child take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.</p> <p>Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, amphetamine sulfate extended-release capsules may affect the way other medicines work and other medicines may affect how dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, amphetamine sulfate extended-release capsules work. Taking dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, amphetamine sulfate extended-release capsules with other medicines can cause serious side effects.</p> <p>Especially tell your healthcare provider if you or your child take:</p> <ul style="list-style-type: none"> • selective serotonin reuptake inhibitors (SSRIs) • serotonin norepinephrine reuptake inhibitors (SNRIs) • medicines used to treat migraine headaches called triptans • tricyclic antidepressants • lithium • fentanyl • tramadol • tryptophan • buspirone • St. John's Wort
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Know the medicines that you or your child take. Keep a list of your medicines with you to show your or your child's healthcare provider and pharmacist when you or your child get a new medicine.

Your healthcare provider will decide whether dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, amphetamine sulfate extended-release capsules can be taken with other medicines. **Do not start any new medicine during treatment with dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, amphetamine sulfate extended-release capsules without talking to your or your child's healthcare provider first.**

How should I take dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, amphetamine sulfate extended-release capsules?

- Take dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, amphetamine sulfate extended-release capsules exactly as prescribed by your healthcare provider.
- Your healthcare provider may change the dose if needed.
- Take dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, amphetamine sulfate extended-release capsules 1 time each day in the morning right after you wake-up. Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, amphetamine sulfate extended-release capsules may last up to 16 hours and can cause difficulty sleeping.
- If you miss a dose of dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, amphetamine sulfate extended-release capsules, **do not** take your dose later in the day or double your dose to make up for a missed dose. Take your dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, amphetamine sulfate extended-release capsules dose the next morning at your regularly scheduled time.
- Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, amphetamine sulfate extended-release capsules can be taken with or without food but take it the same way each time.
- Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, amphetamine sulfate extended-release capsules may be swallowed whole **or** if dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, amphetamine sulfate extended-release capsules cannot be swallowed whole, the capsules may be opened and sprinkled over a spoonful of applesauce.
 - swallow all of the applesauce and medicine mixture right away
 - **do not** chew the applesauce and medicine mixture
 - **do not** store the sprinkled applesauce

If you or your child takes too many dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, 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.

What should I avoid during treatment with dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, amphetamine sulfate extended-release capsules?

You should avoid drinking alcohol during treatment with dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, amphetamine sulfate extended-release capsules.

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

Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, amphetamine sulfate extended-release capsules can cause serious side effects, including:

- See **"What is the most important information I should know about dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, 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, amphetamine sulfate extended-release capsules. Your healthcare provider may stop your child's dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, amphetamine sulfate extended-release capsules treatment if they are not growing or gaining weight as expected.
- **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 have or your child has any numbness, pain, skin color change, or sensitivity to temperature in your fingers or toes.

Call your healthcare provider 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, amphetamine sulfate extended-release capsules.

- **Seizures.** Your healthcare provider will stop treatment with dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, amphetamine sulfate extended-release capsules if you have a seizure.
- **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, amphetamine sulfate extended-release capsules.
- **Serotonin syndrome.** This problem may happen when dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, amphetamine sulfate extended-release capsules are

taken with certain other medicines and may be life-threatening. Call your healthcare provider or go to the nearest hospital emergency room if you get symptoms of serotonin syndrome which may include:

- agitation, hallucinations, coma
- loss of coordination
- flushing
- fast heartbeat
- seizures
- muscle stiffness or tightness
- sweating or fever
- nausea, vomiting, or diarrhea
- dizziness
- changes in blood pressure
- confusion
- high body temperature (hyperthermia)

The most common side effects of dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, amphetamine sulfate extended-release capsules include:

- trouble sleeping
- decreased appetite
- dry mouth
- increased heart rate
- anxiety
- nausea
- irritability
- weight loss

These are not all the possible side effects of dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, 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.

How should I store dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, amphetamine sulfate extended-release capsules?

- Store dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, amphetamine sulfate extended-release capsules at room temperature between 68°F to 77°F (20°C to 25°C).
- Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, amphetamine sulfate extended-release capsules come in a child-resistant package.
- Protect dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, amphetamine sulfate extended-release capsules from light.
- Store dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, 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, 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, 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, amphetamine sulfate extended-release capsules in the household trash. Visit www.fda.gov/drugdisposal for additional information on disposal of unused medicines.

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

General information about the safe and effective use of dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, 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, amphetamine sulfate extended-release capsules for a condition for which it was not prescribed. Do not give dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, 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, amphetamine sulfate extended-release capsules that is written for healthcare professionals.

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

Active ingredients: dextroamphetamine sulfate and amphetamine sulfate, dextroamphetamine saccharate and amphetamine aspartate monohydrate

Inactive ingredients: ammonio methacrylate copolymer (Type B), dibutyl sebacate, ethylcellulose, FD&C Yellow #6, FD&C Blue #2, gelatin, hypromellose, methacrylic acid copolymer (Type-C), polyethylene glycol, sugar spheres, talc, titanium dioxide, triethyl citrate, yellow iron oxide and edible inks. The 37.5 mg strength capsule also contains red iron oxide. The 50 mg strength capsule also contains D&C Red #28, D&C Red #33, and FD&C Blue #1.

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