An electronic copy of this medication guide can be obtained from www.mallinckrodt.com/Medguide/MG20D14.pdf or by calling 1-800-778-7898 for alternate delivery options.

MEDICATION GUIDE
Dextroamphetamine Saccharate,
Amphetamine Aspartate Monohydrate,
Dextroamphetamine Sulfate,
Amphetamine Sulfate Extended-Release Capsules, CII
(dex" troe am fet' a meen sac cha rate, am fet' a meen a spar' tate,
dex" troe am fet' a meen sul' fate, am fet' a meen sul' fate)

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

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

Abuse, misuse, and addiction. Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, 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, 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.

- 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.

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, 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, 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, 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, amphetamine sulfate extended-release capsules, especially hearing voices, seeing or believing things that are not real, or new manic symptoms.

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

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 adults and children 6 years of age and older. Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, amphetamine sulfate extended-release capsules may help increase attention and decrease impulsiveness and hyperactivity in people with ADHD.

Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, amphetamine sulfate extended-release capsules are not recommended for use in children under 6 years of age with ADHD.

Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, amphetamine sulfate extended-release capsules are a federally controlled substance (CII) because they contain 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 them 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.

Do not take dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, 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, 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, amphetamine sulfate extended-release capsules.

Before taking dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, 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, amphetamine sulfate extended-release capsules will harm the unborn baby. Tell your healthcare provider if you or your child become pregnant during treatment with dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, amphetamine sulfate extended-release capsules.
    - 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 of Psychostimulants at 1-866-961-2388 or visit online at https://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/othermedications/.
- are breastfeeding or plan to breastfeed. Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, amphetamine sulfate extended-release capsules passes into breast milk. You or your child should not breastfeed during treatment with dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, 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, 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, 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, amphetamine sulfate extended-release capsules.

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

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

- selective serotonin reuptake inhibitors (SSRIs)
- medicines used to treat migraine headaches called triptans
- lithium
- tramadol
- buspirone
- serotonin norepinephrine reuptake inhibitors (SNRIs)
- tricyclic antidepressants
- fentanyl
- tryptophan
- St. John's Wort

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, amphetamine sulfate extended-release capsules without talking to your healthcare provider first.

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

- Take dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, 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, amphetamine sulfate extended-release capsules 1 time each day in the morning when you first wake up.
- Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, amphetamine sulfate extended-release capsules can be taken with or without food.
- Swallow dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, 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 mixture right away.
    - **Do not** chew the applesauce and medicine mixture.
    - **Do not** store the applesauce sprinkled with dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, amphetamine sulfate extended-release capsules.

If you or your child take 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 are the 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 may 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.
- **Seizures.** Your healthcare provider may stop treatment with dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, 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 have or your child have any numbness, pain, skin color change, or sensitivity to temperature in your fingers or toes.

  Call your healthcare provider right away if you have 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.

- **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. Stop taking dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, 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:
  - agitation, hallucinations, coma, or other changes in mental status
  - problems controlling movements or muscle twitching
  - fast heartbeat
  - seizures
  - loss of coordination
  - confusion
  - dizziness
  - change in blood pressure
  - sweating or fever
  - nausea, vomiting, or diarrhea
  - muscle stiffness or tightness
  - high body temperature (hyperthermia)

- **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.

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

- loss of appetite
- trouble sleeping
- stomach (abdominal) pain
- mood swings
- vomiting
- nervousness
- nausea
- fever

The most common side effects of dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, amphetamine sulfate extended-release capsules in adolescents ages 13 to 17 include:

- loss of appetite
- trouble sleeping
- stomach (abdominal pain)
- weight loss
- nervousness

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

- dry mouth
- loss of appetite
- trouble sleeping
- headache
- weight loss
- nausea
- anxiety
- agitation
- dizziness
- fast heartbeat
- diarrhea
- weakness
- urinary tract infections (UTIs)

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 to 77°F (20 to 25°C).
- 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 they were 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 saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, amphetamine sulfate.

Inactive ingredients: hard gelatin capsules, hydroxypropyl cellulose, methacrylic acid-ethyl acrylate copolymer, sucrose, corn starch, talc, triethyl citrate, sodium lauryl sulfate, and polysorbate 80.

The gelatin capsules for all six strengths contain gelatin, titanium dioxide, sodium lauryl sulfate, and edible inks containing shellac glaze, propylene glycol, ferrosoferric oxide, and black iron oxide. The 5 mg contains FD&C Blue No. 1, D&C Red No. 28, FD&C Yellow 6, and D&C Yellow 10. The 10 mg and 15 mg capsules contain FD&C Blue No. 1 and D&C Red No. 28. The 20 mg, 25 mg, and 30 mg capsules contain FD&C Yellow 6 and D&C Yellow 10.

Manufactured for: SpecGx LLC, Webster Groves, MO 63119 USA

For more information, got to www.mallinckrodt.com or call 1-800-778-7898. Mallinckrodt™

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