

MEDICATION GUIDE
Dextroamphetamine Saccharate
Amphetamine Aspartate
Dextroamphetamine Sulfate
Amphetamine Sulfate Tablets

(Mixed Salts of a Single Entity Amphetamine Product), 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 Mixed Salts of a Single Entity Amphetamine Product?

Mixed Salts of a Single Entity Amphetamine Product may cause serious side effects, including:

- **Abuse, misuse, and addiction.** Mixed Salts of a Single Entity Amphetamine Product has a high chance for abuse and misuse and may lead to substance use problems, including addiction. Misuse and abuse of Mixed Salts of a Single Entity Amphetamine Product, 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 Mixed Salts of a Single Entity Amphetamine Product 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 Mixed Salts of a Single Entity Amphetamine Product and will monitor you or your child during treatment.
 - Mixed Salts of a Single Entity Amphetamine Product may lead to physical dependence after prolonged use, even if taken as directed by your healthcare provider.
 - Do not give Mixed Salts of a Single Entity Amphetamine Product to anyone else. See **"What is Mixed Salts of a Single Entity Amphetamine Product?"** for more information.
 - Keep Mixed Salts of a Single Entity Amphetamine Product in a safe place and properly dispose of any unused medicine. See **"How should I store Mixed Salts of a Single Entity Amphetamine Product?"** 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 Mixed Salts of a Single Entity Amphetamine Product. Tell your healthcare provider if you or your child have any heart problems, heart disease, or heart defects.

Call your healthcare provider right away 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 Mixed Salts of a Single Entity Amphetamine Product.

- **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 Mixed Salts of a Single Entity Amphetamine Product.
- **Mental (psychiatric) problems, including:**
 - 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

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 Mixed Salts of a Single Entity Amphetamine Product, especially hearing voices, seeing or believing things that are not real, or new manic symptoms.

What are Mixed Salts of a Single Entity Amphetamine Product?

Mixed Salts of a Single Entity Amphetamine Product are a central nervous system (CNS) stimulant prescription medicine used for the treatment of:

- Attention Deficit Hyperactivity Disorder (ADHD) in children 3 to 17 years of age. Mixed Salts of a Single

Entity Amphetamine Product may help increase attention and decrease impulsiveness and hyperactivity in people with ADHD.

- a sleep disorder called Narcolepsy in people 6 years and older.

It is not known if Mixed Salts of a Single Entity Amphetamine Product is safe and effective in children with ADHD under 3 years of age.

It is not known if Mixed Salts of a Single Entity Amphetamine Product is safe and effective in children with narcolepsy under 6 years of age.

Mixed Salts of a Single Entity Amphetamine Product 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 Mixed Salts of a Single Entity Amphetamine Product in a safe place to protect it from theft. Never give your Mixed Salts of a Single Entity Amphetamine Product to anyone else because it may cause death or harm them. Selling or giving away Mixed Salts of a Single Entity Amphetamine Product may harm others and is against the law.

Do not take Mixed Salts of a Single Entity Amphetamine Product if you or your child:

- are allergic to amphetamine products or any of the ingredients in Mixed Salts of a Single Entity Amphetamine Product. See the end of this Medication Guide for a complete list of ingredients in Mixed Salts of a Single Entity Amphetamine Product.
- 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.

Before taking Mixed Salts of a Single Entity Amphetamine Product 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, including end stage renal disease (ERSD)
- have seizures or have had an abnormal brain wave test (EEG)
- have circulation problems in fingers or 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 Mixed Salts of a Single Entity Amphetamine Product will harm the unborn baby. Tell your healthcare provider if you or your child become pregnant during treatment with Mixed Salts of a Single Entity Amphetamine Product.
- are breastfeeding or plan to breastfeed. Mixed Salts of a Single Entity Amphetamine Product passes into breast milk. You or your child should not breastfeed during treatment with Mixed Salts of a Single Entity Amphetamine Product. Talk to your healthcare provider about the best way to feed the baby during treatment with Mixed Salts of a Single Entity Amphetamine Product.

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. Mixed Salts of a Single Entity Amphetamine Product 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 Mixed Salts of a Single Entity Amphetamine Product.

Your healthcare provider will decide if Mixed Salts of a Single Entity Amphetamine Product 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) | • serotonin norepinephrine reuptake inhibitors (SNRIs) |
| • medicines used to treat migraine headaches called triptans | • tricyclic antidepressants |
| • lithium | • fentanyl |
| • tramadol | • tryptophan |
| • buspirone | • 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 Mixed Salts of a Single Entity Amphetamine Product without talking to your healthcare provider first.

How should Mixed Salts of a Single Entity Amphetamine Product be taken?

- Take Mixed Salts of a Single Entity Amphetamine Product exactly as prescribed by your or your child's healthcare provider.
- Your healthcare provider may change the dose if needed.
- The first dose of the day is usually taken when you first wake up.
- Mixed Salts of a Single Entity Amphetamine Product can be taken with or without food.
- Your healthcare provider may sometimes stop Mixed Salts of a Single Entity Amphetamine Product treatment for a while to check ADHD symptoms.

If you or your child take too much Mixed Salts of a Single Entity Amphetamine Product 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 while taking Mixed Salts of a Single Entity Amphetamine Product?

Do not drive, operate heavy machinery, or do other potentially dangerous activities until you know how Mixed Salts of a Single Entity Amphetamine Product affects you.

What are possible side effects of Mixed Salts of a Single Entity Amphetamine Product?

Mixed Salts of a Single Entity Amphetamine Product may cause serious side effects, including:

See "What is the most important information I should know about Mixed Salts of a Single Entity Amphetamine Product?"

- **Slowing of growth (height and weight) in children.** Children should have their height and weight checked often during treatment with Mixed Salts of a Single Entity Amphetamine Product. Your healthcare provider may stop your child's Mixed Salts of a Single Entity Amphetamine Product treatment if they are not growing or gaining weight as expected.
- **Seizures.** Your healthcare provider may stop treatment with Mixed Salts of a Single Entity Amphetamine Product 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 has 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 Mixed Salts of a Single Entity Amphetamine Product.

- **Serotonin syndrome.** This problem may happen when Mixed Salts of a Single Entity Amphetamine Product is taken with certain other medicines and may be life-threatening. Stop taking Mixed Salts of a Single Entity Amphetamine Product 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	○ confusion
○ fast heartbeat	○ dizziness
○ flushing	○ changes in blood pressure
○ seizures	○ sweating or fever
○ loss of coordination	○ 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 Mixed Salts of a Single Entity Amphetamine Product.

The most common side effects of Mixed Salts of a Single Entity Amphetamine Product include:

- stomachache
- decreased appetite

- nervousness

Talk to your doctor if you or your child have side effects that are bothersome or do not go away.

These are not all of the possible side effects of Mixed Salts of a Single Entity Amphetamine Product.

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 Mixed Salts of a Single Entity Amphetamine Product?

- Store Mixed Salts of a Single Entity Amphetamine Product at room temperature between 68 to 77°F (20 to 25°C).
- Protect Mixed Salts of a Single Entity Amphetamine Product from light.
- Store Mixed Salts of a Single Entity Amphetamine Product in a safe place, like a locked cabinet.
- Dispose of remaining, unused, or expired Mixed Salts of a Single Entity Amphetamine Product 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 Mixed Salts of a Single Entity Amphetamine Product 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 Mixed Salts of a Single Entity Amphetamine Product in the household trash. Visit www.fda.gov/drugdisposal for additional information on disposal of unused medicines.

Keep Mixed Salts of a Single Entity Amphetamine Product and all medicines out of the reach of children.

General information about the safe and effective use of Mixed Salts of a Single Entity Amphetamine Product

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Mixed Salts of a Single Entity Amphetamine Product for a condition for which they were not prescribed. Do not give Mixed Salts of a Single Entity Amphetamine Product 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 Mixed Salts of a Single Entity Amphetamine Product that is written for healthcare professionals.

What are the ingredients in Mixed Salts of a Single Entity Amphetamine Product?

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

Inactive Ingredients: microcrystalline cellulose, silicon dioxide, povidone and stearic acid

For more information about Mixed Salts of a Single Entity Amphetamine Product, please contact Mallinckrodt at 1-800-778-7898.

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

Mallinckrodt™

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

Revised 10/2023
L20D11