

MEDICATION GUIDE

Dextroamphetamine Saccharate, Amphetamine Aspartate Monohydrate,

Dextroamphetamine Sulfate, Amphetamine Sulfate Tablets (Mixed Salts of a Single Entity Amphetamine Product) CII

(dex-troe-am-FET-ah-meen)

Read the Medication Guide that comes with Mixed Salts of a Single Entity Amphetamine Product 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 Mixed Salts of a Single Entity Amphetamine Product.

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

The following have been reported with use of Mixed Salts of a Single Entity Amphetamine Product and other 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. Mixed Salts of a Single Entity Amphetamine Product.

Your doctor should check you or your child's blood pressure and heart rate regularly during treatment with Mixed Salts of a Single Entity Amphetamine Product.

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 Mixed Salts of a Single Entity Amphetamine Product.

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 Mixed Salts of a Single Entity Amphetamine Product, 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 color 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 signs of unexplained wounds appearing on fingers or toes while taking Mixed Salts of a Single Entity Amphetamine Product.

What are Mixed Salts of a Single Entity Amphetamine Product?

Mixed Salts of a Single Entity Amphetamine Product are a central nervous system stimulant prescription medicine. **It is used for the treatment of Attention-Deficit Hyperactivity Disorder(ADHD).** Mixed Salts of a Single Entity Amphetamine Product may help increase attention and decrease impulsiveness and hyperactivity in patients with ADHD.

Mixed Salts of a Single Entity Amphetamine Product should be used as a part of a total treatment program for ADHD that may include counseling or other therapies.

Mixed Salts of a Single Entity Amphetamine Product are also used in the treatment of a sleep disorder called narcolepsy.

Mixed Salts of a Single Entity Amphetamine Product are a federally controlled substance (CII) because it can be abused or lead to dependence. Keep Mixed Salts of a Single Entity Amphetamine Product in a safe place to prevent misuse and abuse. Selling or giving away Mixed Salts of a Single Entity Amphetamine Product 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 Mixed Salts of a Single Entity Amphetamine Product?

Mixed Salts of a Single Entity Amphetamine Product 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
- are sensitive to, allergic to, or had a reaction to other stimulant medicines

Mixed Salts of a Single Entity Amphetamine Product are not recommended for use in children less than 3 years old.

Mixed Salts of a Single Entity Amphetamine Product may not be right for you or your child. Before starting Mixed Salts of a Single Entity Amphetamine Product tell your or your child's doctor about all health conditions (or a family history of) including:

- heart problems, heart defects, high blood pressure
- mental problems including psychosis, mania, bipolar illness, or depression
- tics or Tourette's syndrome
- liver or kidney problems
- circulation problems in fingers and toes
- thyroid problems
- seizures or have had an abnormal brain wave test (EEG)

Tell your doctor if you or your child are pregnant, planning to become pregnant, or breastfeeding.

Can Mixed Salts of a Single Entity Amphetamine Product be taken with other medicines?

Tell your doctor about all of the medicines that you or your child take including prescription and nonprescription 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 adjusted while taking Mixed Salts of a Single Entity Amphetamine Product.

Your doctor will decide whether Mixed Salts of a Single Entity Amphetamine Product can be taken with other medicines.

Especially tell your doctor if you or your child take:

- anti-depression medicines including MAOIs
- blood pressure medicines
- seizure medicines
- blood thinner medicines
- cold or allergy medicines that contain decongestants
- stomach acid medicines

Know the medicines that you or your child take. Keep a list of your medicines with you to show your doctor and pharmacist.

Do not start any new medicine while taking Mixed Salts of a Single Entity Amphetamine Product without talking to your doctor 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.** Your doctor may adjust the dose until it is right for you or your child.
- Mixed Salts of a Single Entity Amphetamine Product are usually taken two to three times a day. The first dose is usually taken when you first wake in the morning. One or two more doses may be taken during the day, 4 to 6 hours apart.
- Mixed Salts of a Single Entity Amphetamine Product can be taken with or without food.
- From time to time, your doctor may stop Mixed Salts of a Single Entity Amphetamine Product treatment for a while to check ADHD symptoms.
- Your doctor may do regular checks of the blood, heart, and blood pressure while taking Mixed Salts of a Single Entity Amphetamine Product. Children should have their height and weight checked often while taking Mixed Salts of a Single Entity Amphetamine Product. Mixed Salts of a Single Entity Amphetamine Product treatment may be stopped if a problem is found during these check-ups.
- **If you or your child take too much Mixed Salts of a Single Entity Amphetamine Product or overdoses, call your doctor or poison control center right away, or get emergency treatment.**

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

See “**What is the most important information I should know about Mixed Salts of a Single Entity Amphetamine Product?**” 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	• nervousness
• decreased appetite	• trouble sleeping
• stomach ache	• dizziness

Mixed Salts of a Single Entity Amphetamine Product may affect you or your child’s ability to drive or do other dangerous activities.

Talk to your doctor if you or your child have 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.

How should I store Mixed Salts of a Single Entity Amphetamine Product?

- Store Mixed Salts of a Single Entity Amphetamine Product in a safe place at room temperature, 20° to 25° C (68° to 77° F).
- **Keep Mixed Salts of a Single Entity Amphetamine Product and all medicines out of the reach of children.**

General information about 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 it was 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.

This Medication Guide summarizes the most important information about Mixed Salts of a Single Entity Amphetamine Product. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about Mixed Salts of a Single Entity Amphetamine Product that was written for healthcare professionals. For additional information on Mixed Salts of a Single Entity Amphetamine Product, please contact Sandoz Inc. at 1-800-525-8747 .

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

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

Inactive Ingredients: lactose monohydrate, pregelatinized starch (corn) and magnesium stearate.

In addition the 5 mg and 10 mg tablets contain FD&C blue No. 1 aluminum lake and the 20 mg and 30 mg tablets contain FD&C yellow No. 6 aluminum lake as color additives.

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

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

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

Manufactured for

Sandoz Inc.

Princeton, NJ 08540

Manufactured by

Epic Pharma, LLC

Laurelton, NY 11413

OS7848

REV. 02/15

MF0084REV02/15

MG #34744