MEDICATION GUIDE

Amphetamine Sulfate Tablets, CII

(am fet' a meen sul' fate)

What is the most important information I should know about amphetamine sulfate tablets?
Amphetamine sulfate tablets may cause serious side effects, including:

- **Abuse, misuse, and addiction.** Amphetamine sulfate tablets have a high chance for abuse and misuse and may lead to substance use problems, including addiction. Misuse and abuse of amphetamine sulfate tablets, other amphetamine containing medicines, and methylphenidate, can lead to overdose and death. The risk of overdose and death is increased with higher doses of amphetamine sulfate tablets 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 amphetamine sulfate tablets and will monitor you or your child during treatment.
  - Amphetamine sulfate tablets may lead to physical dependence after prolonged use, even if taken as directed by your healthcare provider.
  - Do not give amphetamine sulfate tablets to anyone else. See **"What are amphetamine sulfate tablets?"** for more information.
  - Keep amphetamine sulfate tablets in a safe place and properly dispose of unused medicine. See **"How should I store amphetamine sulfate tablets?"** 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 amphetamine sulfate tablets. 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 amphetamine sulfate tablets.

- **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 amphetamine sulfate tablets.

- **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 amphetamine sulfate tablets, especially hearing voices, seeing or believing things that are not real, or new manic symptoms.

What are amphetamine sulfate tablets?
Amphetamine sulfate tablets are a central nervous system (CNS) stimulant prescription medicine used for the treatment of:

- a sleep disorder called narcolepsy.
- Attention Deficit Hyperactivity Disorder (ADHD).

- Amphetamine sulfate tablets may help increase attention and decrease impulsiveness and hyperactivity in people with ADHD.
- exogenous obesity. Amphetamine sulfate tablets may be used as part of a short-term (a few weeks) weight reduction program for obesity in people who have not responded to other treatment.

Amphetamine sulfate tablets are not for use in children with ADHD under 3 years of age.

It is not known if amphetamine sulfate tablets are safe and effective in children not for use as an anorectic agent for with exogenous obesity in children under less than 12 years of age.

Amphetamine sulfate tablets 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 amphetamine sulfate tablets in a safe place to protect it from theft. Never give your amphetamine sulfate tablets to anyone else, because it may cause death or harm them. Selling or giving away amphetamine sulfate tablets may harm others and is against the law.

Do not take amphetamine sulfate tablets if you or your child:

- are allergic to amphetamine products or any of the ingredients in amphetamine sulfate tablets. See the end of this Medication Guide for a complete list of ingredients in amphetamine sulfate tablets.
- are taking or have taken within the past 14 days a medicine used to treat depression called a monoamine oxidase inhibitor (MAOI).

Before taking amphetamine sulfate tablets 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 circulation problems in fingers and toes
- have or have had seizures
- 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 amphetamine sulfate tablets will harm the unborn baby. Tell your healthcare provider if you or your child become pregnant during treatment with amphetamine sulfate tablets.
- are breastfeeding or plan to breastfeed. Amphetamine sulfate passes into breast milk. You or your child should not breastfeed during treatment with amphetamine sulfate tablets. Talk to your healthcare provider about the best way to feed the baby during treatment with amphetamine sulfate tablets.

Tell your healthcare provider about all of the medicines that you or your child takes, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Amphetamine sulfate tablets and some medicines may interact with each other and cause serious side effects. Sometimes the doses of other medicines will need to be adjusted during treatment with amphetamine sulfate tablets.

Your healthcare provider will decide if amphetamine sulfate tablets can be taken with other medicines.

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

- 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 takes.

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 amphetamine sulfate tablets without talking to your healthcare provider first.

How should amphetamine sulfate tablets be taken?

- Take amphetamine sulfate tablets 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.
- Amphetamine sulfate tablets may cause problems sleeping if taken late in the evening.
- Amphetamine sulfate tablets should be taken 30 to 60 minutes before meals if it is being used to treat exogenous obesity.

If you or your child take too many amphetamine sulfate tablets 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 amphetamine sulfate tablets?

Do not drive, operate machinery, or do other dangerous activities until you know how amphetamine sulfate tablets affect you.

What are the possible side effects of amphetamine sulfate tablets?

Amphetamine sulfate tablets may cause serious side effects, including:

- See **"What is the most important information I should know about amphetamine sulfate tablets?"**.
- **Slowing of growth (height and weight) in children.** Children should have their height and weight checked often during treatment with amphetamine sulfate tablets. Your healthcare provider may stop your child's amphetamine sulfate tablets treatment if they are not growing or gaining weight as expected.
- **Seizures.** Your healthcare provider may stop treatment with amphetamine sulfate tablets 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 any numbness, pain, skin color change, or sensitivity to temperature in the 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 amphetamine sulfate tablets.
- **Serotonin syndrome.** This problem may happen when amphetamine sulfate tablets are taken with certain other medicines and may be life-threatening. 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
  - fast heartbeat
  - flushing
  - seizures
  - sweating or fever
  - loss of coordination
  - confusion
  - dizziness
  - muscle stiffness or tightness
  - changes in blood pressure
  - high body temperature (hyperthermia)
  - nausea, vomiting, diarrhea
- **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 amphetamine sulfate tablets.

The most common side effects of amphetamine sulfate tablets include:

- headache
- stomachache
- trouble sleeping
- decreased appetite
- nervousness
- dizziness
- sexual problems (impotence in males)
- itching
- diarrhea or constipation
- dry mouth
- weight loss

- unpleasant taste
- vomiting
- mood swing

These are not all the possible side effects of amphetamine sulfate tablets.
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 amphetamine sulfate tablets?

- Store amphetamine sulfate tablets at room temperature between 68°F to 77°F (20°C to 25°C).
- Store amphetamine sulfate tablets in a safe place, like a locked cabinet.
- Dispose of remaining, unused, or expired amphetamine sulfate tablets 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 amphetamine sulfate tablets 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 amphetamine sulfate tablets in the household trash. Visit www.fda.gov/drugdisposal for additional information on disposal of unused medicines.

Keep amphetamine sulfate tablets and all medicines out of the reach of children.

General information about the safe and effective use of amphetamine sulfate tablets.
Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use amphetamine sulfate tablets for a condition for which they were not prescribed. Do not give amphetamine sulfate tablets to other people, even if they have the same symptoms that you or your child have. It may harm them and it is against the law. You can ask your pharmacist or healthcare provider for information about amphetamine sulfate tablets that is written for health professionals.

What are the ingredients in amphetamine sulfate tablets?
Active Ingredient: amphetamine sulfate
Inactive Ingredients: crospovidone, silicified microcrystalline cellulose, silicon dioxide, and stearic acid. The 10 mg tablet also contains FD&C Blue #1.

Manufactured by: SpecGx LLC, Webster Groves, MO 63119 USA,
www.mallinckrodt.com or call 1-800-778-7898

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