MEDICATION GUIDE
MYDAYIS (my-DAY-is)
(mixed salts of a single-entity amphetamine product)
extended-release capsules, CII

What is the most important information I should know about MYDAYIS?
MYDAYIS can cause serious side effects, including:

- **Abuse and dependence.** MYDAYIS, other amphetamine containing medicines, and methylphenidate have a high chance for abuse and can cause physical and psychological dependence. Your healthcare provider should check you or your child for signs of abuse and dependence before and during treatment with MYDAYIS.
  - Tell your healthcare provider if you or your child have ever abused or been dependent on alcohol, prescription medicines or street drugs.
  - Your healthcare provider can tell you more about the differences between physical and psychological dependence and drug addiction.

- **Heart-related problems, including:**
  - sudden death, stroke, and heart attack in adults
  - sudden death in people who have heart problems or heart defects
  - increased blood pressure and heart rate
Your healthcare provider should check you or your child carefully for heart problems before starting MYDAYIS. Tell your healthcare provider if you or your child have any heart problems, heart defects, high blood pressure, or a family history of these problems.
Your healthcare provider should check you or your child’s blood pressure and heart rate regularly during treatment with MYDAYIS.

Call your healthcare provider or go to the nearest hospital emergency room right away if you or your child has any signs of heart problems such as chest pain, shortness of breath, or fainting during treatment with MYDAYIS.

- **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 while taking MYDAYIS, especially hearing voices, seeing or believing things that are not real, or new manic symptoms.

What is MYDAYIS?
MYDAYIS is 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.

MYDAYIS is not for use in children 12 years of age and younger.

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

Do not take MYDAYIS if you or your child are:

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

Before taking MYDAYIS, tell your or your child’s healthcare provider about all medical conditions, including if you or your child:

- have heart problems, 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. You should not take MYDAYIS if you have end stage renal disease (ESRD).
- are pregnant or plan to become pregnant. It is not known if MYDAYIS will harm your unborn baby. Tell your healthcare provider if you become pregnant during treatment with MYDAYIS.
  - There is a pregnancy registry for females who are exposed to MYDAYIS during pregnancy. The purpose of the registry is to collect information about the health of females exposed to MYDAYIS and their baby. If you or your child becomes pregnant during treatment with MYDAYIS, 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://womensmental-health.org/research/pregnancyregistry/.
- are breastfeeding or plan to breastfeed. MYDAYIS passes into breast milk. You should not breastfeed during treatment with MYDAYIS.

Tell your healthcare provider about all the medicines that you or your child takes, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

MYDAYIS may affect the way other medicines work and other medicines may affect how MYDAYIS works. Taking MYDAYIS with other medicines can cause serious side effects.

Especially tell your healthcare provider if you or your child take medicines used to treat depression including MAOIs.

Know the medicines that you or your child takes. 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 MYDAYIS can be taken with other medicines. Do not start any new medicine during treatment with MYDAYIS without talking to your or your child’s healthcare provider first.

How should I take MYDAYIS?
• Take MYDAYIS exactly as prescribed by your healthcare provider.
• Your healthcare provider may change the dose if needed.
• Take MYDAYIS 1 time each day in the morning right after you wake-up. MYDAYIS may last up to 16 hours and can cause difficulty sleeping.
• If you miss a dose of MYDAYIS, do not take your dose later in the day or double your dose to make up for a missed dose. Take your MYDAYIS dose the next morning at your regularly scheduled time.
• MYDAYIS can be taken with or without food but take it the same way each time.
• MYDAYIS capsules may be swallowed whole or if MYDAYIS capsules cannot be swallowed whole, the capsules may be opened and sprinkled over a spoonful of applesauce.
  o swallow all of the applesauce and medicine mixture right away
  o do not chew the applesauce and medicine mixture
  o do not store the sprinkled applesauce
• Your healthcare provider may sometimes stop MYDAYIS treatment for a while to check ADHD symptoms.
• If you or your child takes too much MYDAYIS, call your healthcare provider or go to the nearest hospital emergency room right away.

What should I avoid during treatment with MYDAYIS? You should avoid drinking alcohol during treatment with MYDAYIS.

What are possible side effects of MYDAYIS? MYDAYIS can cause serious side effects, including:
• See “What is the most important information I should know about MYDAYIS?”
• Slowing of growth (height and weight) in children. Children should have their height and weight checked often during treatment with MYDAYIS. Your healthcare provider may stop your child’s MYDAYIS 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:
  o fingers or toes may feel numb, cool, painful
  o 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 MYDAYIS.
• Seizures. Your healthcare provider will stop treatment with MYDAYIS if you have a seizure.
• Serotonin syndrome. This problem may happen when MYDAYIS is 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:
  o agitation, hallucinations, coma, or other changes in mental status
  o problems controlling your movements or muscle twitching
  o fast heartbeat
  o sweating or fever
  o nausea, vomiting, or diarrhea
  o muscle stiffness or tightness

The most common side effects of MYDAYIS include:
• trouble sleeping
• decreased appetite
• dry mouth
• increased heart rate
• anxiety
• nausea
• irritability
• weight loss
These are not all the possible side effects of MYDAYIS. 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 MYDAYIS?
• Store MYDAYIS at room temperature between 68°F to 77°F (20°C to 25°C).
• Protect MYDAYIS from light.
• Store MYDAYIS in a safe place, like a locked cabinet.
• Dispose of remaining, unused, or expired MYDAYIS by a medicine take-back program at authorized collection sites such as retail pharmacies, hospital or clinic pharmacies, and law enforcement locations. If no take-back program or authorized collector is available, mix MYDAYIS 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 MYDAYIS in the household trash.

Keep MYDAYIS and all medicines out of the reach of children.

General information about the safe and effective use of MYDAYIS
Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use MYDAYIS for a condition for which it was not prescribed. Do not give MYDAYIS 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 MYDAYIS that was written for healthcare professionals.

What are the ingredients in MYDAYIS?
Active ingredients: dextroamphetamine sulfate and amphetamine sulfate, dextroamphetamine saccharate and amphetamine aspartate monohydrate
Inactive ingredients: hard gelatin capsules, ethylcellulose, hydroxypropyl methylcellulose, methacrylic acid copolymer, methyl acrylate, methyl methacrylate, opadry beige, sugar spheres, talc, and triethyl citrate. Gelatin capsules contain gelatin, titanium dioxide, yellow iron oxide and edible inks. The 12.5 mg and 25 mg capsules also contain FD&C Blue #2. The 37.5 mg also contains red iron oxide. The 50 mg capsule also contains D&C Red #28, D&C Red #33, and FD&C Blue #1.

Manufactured for: Shire US Inc., 300 Shire Way, Lexington, MA 02421. MYDAYIS is a trademark of Shire LLC. ©2017 Shire. All rights reserved.
For more information about MYDAYIS go to www.mydayis.com or call 1-800-828-2088.
This Medication Guide has been approved by the U.S. Food and Drug Administration Issued: 09/2019 S52739