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Lisdexamfetamine

pronounced as (lis dex am fet' a meen)

IMPORTANT WARNING:

Lisdexamfetamine can be habit–forming. Do not take a larger dose, take it more often, take it for a longer time, or take it in a different way than prescribed by your doctor. If you take too much lisdexamfetamine, you may feel a need to continue to take large amounts of the medication, and you may experience symptoms such as unusual changes in your behavior. You or your caregiver should tell your doctor immediately, if you experience any of the following symptoms: fast, pounding, or irregular heartbeat; sweating; dilated pupils; abnormally excited mood; irritability; restlessness; difficulty falling sleeping or staying asleep; hostility; aggression; anxiety; loss of appetite; loss of coordination; uncontrollable movement of a part of the body; flushed skin; vomiting; stomach pain; or thinking about harming or killing oneself or others or planning or trying to do so. Overusing lisdexamfetamine may also cause sudden death or serious heart problems, such as heart attack or stroke.

Tell your doctor if you or anyone in your family drinks or has ever drunk large amounts of alcohol, uses or has ever used street drugs, or has overused prescription medications. Your doctor will probably not prescribe lisdexamfetamine for you.

Do not suddenly stop taking lisdexamfetamine without talking to your doctor, especially if you have overused the medication. Your doctor will probably decrease your dose gradually and monitor you carefully during this time. You may develop severe depression and extreme tiredness if you suddenly stop taking lisdexamfetamine after overusing it.

Do not sell, give away, or let anyone else take your medication. Selling or giving away lisdexamfetamine may harm others and is against the law. Store lisdexamfetamine in a safe place so that no one else can take it accidentally or on purpose. Keep track of how many capsules are left so you will know if any are missing.

Your doctor or pharmacist will give you the manufacturer's patient information sheet (Medication Guide) when you begin treatment with lisdexamfetamine and each time you get more medication. Read the information carefully and ask your doctor or pharmacist if you have any questions. You can also visit the Food and Drug Administration (FDA) website (http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm
[http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm]) or the manufacturer's website to obtain the Medication Guide.

Why is this medication prescribed?

Lisdexamfetamine is used as part of a treatment program to control symptoms of attention deficit hyperactivity disorder (ADHD; more difficulty focusing, controlling actions, and remaining still or quiet than other people who are the same age) in adults and children 6 years of age and older. Lisdexamfetamine is also used in adults to treat binge eating disorder (an eating disorder characterized by periods of uncontrolled overeating). Lisdexamfetamine is in a class of medications called central nervous system stimulants. It works by changing the amounts of certain natural substances in the brain.

How should this medicine be used?

Lisdexamfetamine comes as a capsule and a chewable tablet to be taken by mouth. It is usually taken once a day in the morning with or without food. Take lisdexamfetamine at around the same time every day. Do not take lisdexamfetamine in the late afternoon or evening because it may cause difficulty falling asleep or staying asleep. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take lisdexamfetamine exactly as directed.

Chewable tablets should be chewed thoroughly before being swallowed.

You may swallow the capsule whole, or you may open the capsule, sprinkle the entire contents into yogurt, a glass of water, or orange juice. Stir to dissolve and swallow the mixture right away. Do not store the mixture for future use, and do not divide the contents of one capsule into more than one dose.

Your doctor will probably start you on a low dose of lisdexamfetamine and increase your dose gradually, not more often than once every week. Your doctor may decrease your dose if you experience unpleasant side effects.

Your doctor may tell you to stop taking lisdexamfetamine from time to time to see if the medication is still needed. Follow these directions carefully.

Other uses for this medicine

Lisdexamfetamine should not be used for weight loss in people who are obese or who are overweight.

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before taking lisdexamfetamine,

- tell your doctor and pharmacist if you are allergic to lisdexamfetamine; other stimulant medications such as amphetamine (in Adderall), benzphetamine (Didrex), dextroamphetamine (in Adderall, Dexedrine, Dextrostat), methamphetamine (Desoxyn); any other medications, or any of the ingredients in lisdexamfetamine capsules. Ask your doctor or pharmacist or check the manufacturer's information for a list of the ingredients.
- tell your doctor if you are taking a monoamine oxidase (MAO) inhibitor such as isocarboxazid (Marplan), linezolid (Zyvox), methylene blue, phenelzine (Nardil), selegiline (Eldepryl, Emsam, Zelapar), and tranylcypromine (Parnate), or if you have stopped taking one of these medications during the past 2 weeks. Your doctor will probably tell you not to take lisdexamfetamine until at least 14 days have passed since you last took an MAO inhibitor.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking. Be sure to mention any of the following: acetazolamide (Diamox), ascorbic acid (Vitamin C), other medications for ADHD, sodium bicarbonate (Arm and Hammer Baking Soda, Soda Mint), and sodium phosphate (OsmoPrep, Visicol). Your doctor may need to change the doses of your medications or monitor you carefully for side effects. Many other medications may also interact with lisdexamfetamine, so be sure to tell your doctor about all the medications you are taking, even those that do not appear on this list.
- tell your doctor if anyone in your family has or has ever had an irregular heartbeat or has died suddenly. Also tell your doctor if you have recently had a heart attack and if you have or have ever had a heart defect, high blood pressure, an irregular heartbeat, hardening of the arteries, or other heart problems. Your doctor will examine you to see if your heart and blood vessels are healthy before you start taking lisdexamfetamine and will check your heart and blood pressure regularly during your treatment with lisdexamfetamine. Your doctor will probably tell you not to take lisdexamfetamine if you have a heart condition or if there is a high risk that you may develop a heart condition.
- tell your doctor if you or anyone in your family has or has ever had depression, bipolar disorder (mood that changes from depressed to abnormally excited), or mania (frenzied, abnormally excited mood), motor tics (repeated uncontrollable movements), verbal tics (repetition of sounds or words that is hard to control), or Tourette's syndrome (a condition characterized by the need to perform repeated motions or to repeat sounds or words), or has thought about or attempted suicide Also tell your doctor if you have or have ever had Raynaud's disease (problems with blood flow to the fingers, toes, ears, and nose), mental illness, seizures, an abnormal electroencephalogram (EEG; a test that measures electrical activity in the brain),

glaucoma (increased pressure in the eye that may cause vision loss), hyperthyroidism (condition in which there is too much thyroid hormone in the body), or kidney disease.

- tell your doctor if you are pregnant, plan to become pregnant, or are breastfeeding. If you become pregnant while taking lisdexamfetamine, call your doctor.
- talk to your doctor about the risks and benefits of taking lisdexamfetamine if you are 65 years of age or older. Older adults should not usually take lisdexamfetamine because it is not as safe as other medications that can be used to treat the same condition.
- you should know that this medication may make it difficult for you to perform activities that require alertness or physical coordination. Do not drive a car or operate machinery until you know how this medication affects you.
- you should know that lisdexamfetamine should be used as part of a total treatment program for ADHD, which may include counseling and special education. Make sure to follow all of your doctor's and/or therapist's instructions.

What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

What should I do if I forget a dose?

Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

What side effects can this medication cause?

Lisdexamfetamine may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- sleepiness
- dizziness
- headache
- dry mouth
- constipation
- diarrhea
- nausea
- weight loss

Some side effects can be serious. If you experience any of these symptoms or those listed in the IMPORTANT WARNING section, stop taking lisdexamfetamine and call your doctor immediately or get emergency medical treatment:

• slow or difficult speech

- · weakness or numbness of an arm or leg
- seizures
- hallucinating (seeing things or hearing voices that do not exist)
- believing things that are not true
- feeling unusually suspicious of others
- mood swings
- motor or verbal tics
- hives
- rash
- swelling of the eyes, face, tongue, lips, or mouth
- blurred vision or other vision problems
- paleness or blue color of fingers or toes
- numbness, pain, or sensitivity to temperature in the fingers or toes
- unexplained wounds appearing on fingers or toes

Lisdexamfetamine may cause sudden death in children and teenagers, especially children and teenagers who have heart defects or serious heart problems. This medication also may cause sudden death, heart attack or stroke in adults, especially adults who have heart defects or serious heart problems. Call your doctor right away if you or your child has any signs of heart problems while taking this medication including: chest pain, shortness of breath, or fainting. Talk to your doctor about the risks of taking this medication.

Lisdexamfetamine may slow children's growth or weight gain. Your child's doctor will watch his or her growth carefully. Talk to your child's doctor if you have concerns about your child's growth or weight gain while he or she is taking this medication. Talk to your child's doctor about the risks of giving lisdexamfetamine to your child.

Lisdexamfetamine may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (http://www.fda.gov/Safety/MedWatch [http://www.fda.gov/Safety/MedWatch]) or by phone (1-800-332-1088).

What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom).

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. http://www.upandaway.org
[http://www.upandaway.org]

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (http://goo.gl/c4Rm4p [http://goo.gl/c4Rm4p]) for more information if you do not have access to a take-back program.

In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at https://www.poisonhelp.org/help [https://www.poisonhelp.org/help]. If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

Symptoms of overdose may include the following:

- restlessness
- confusion
- aggressive behavior
- feelings of panic
- hallucination (seeing things or hearing voices that do not exist)
- fast breathing
- uncontrollable shaking of a part of the body
- fever
- muscle weakness or aching
- tiredness or weakness
- depression
- fast or irregular heartbeat
- nausea
- vomiting
- diarrhea

- stomach cramps
- seizures
- coma (loss of consciousness for a period of time)

What other information should I know?

Keep all appointments with your doctor and the laboratory. Your doctor may order certain lab tests to check your body's response to lisdexamfetamine.

Before having any laboratory test, tell your doctor and the laboratory personnel that you are taking lisdexamfetamine.

This prescription is not refillable. Be sure to schedule appointments with your doctor on a regular basis so that you do not run out of medication.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

Vyvanse ®

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