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Patient Handout

Patient Education

amphetamine-dextroamphetamine Oral

IMPORTANT: HOW TO USE THIS INFORMATION: This is a summary and does NOT have all possible information about this product. This information does not assure that this product is safe, effective, or appropriate for you. This information is not individual medical advice and does not substitute for the advice of your health care professional. Always ask your health care professional for complete information about this product and your specific health needs.

AMPHETAMINE/DEXTROAMPHETAMINE - ORAL

(am-FET-a-meen/DEX-troe-am-FET-a-meen)

COMMON BRAND NAME(S): Adderall

WARNING: Misuse or abuse of amphetamine may result in serious (possibly fatal) heart and blood pressure problems. Amphetamine-type medications can be habit-forming. Use only as directed. With prolonged use, drug dependence may occur, and withdrawal symptoms may occur after stopping the drug. Consult your doctor or pharmacist for more details.

USES

This combination medication is used as part of a total treatment program to control attention deficit hyperactivity disorder (ADHD). It may help to increase the ability to pay attention, stay focused, and control behavior problems.

This product is a combination of stimulants (amphetamine and dextroamphetamine). It is thought to work by restoring the balance of certain natural substances (neurotransmitters) in the brain.

This drug may also be used to treat certain sleeping disorders (narcolepsy). It should not be used to treat tiredness or to hold off sleep in people who do not have a sleep disorder.

HOW TO USE:

Read the Medication Guide provided by your pharmacist before you start using amphetamine/dextroamphetamine and each time you get a refill. If you have any questions, consult your doctor or pharmacist.

Take this medication by mouth, usually when you first wake up in the morning or as directed by your doctor. If additional doses are prescribed, take them 4-6 hours apart. Taking this medication less than 6 hours before bedtime may cause trouble sleeping. Take this medication exactly as prescribed.

The dosage is based on your medical condition and response to therapy. Your doctor may adjust your dose to find the dose that is best for you. Follow your doctor's instructions carefully.

Use this medication regularly and exactly as prescribed in order to get the most benefit from it. To help you remember, use it at the same time each day.

This medication may cause withdrawal reactions, especially if it has been used regularly for a long time (more than a few weeks) or in high doses. In such cases, withdrawal symptoms (such as severe tiredness, mood changes including depression, and sleep problems) may occur if you suddenly stop using this medication. To prevent

withdrawal reactions, your doctor may reduce your dose gradually. Consult your doctor or pharmacist for more details, and report any withdrawal reactions immediately.

Though it is unlikely to occur, this medication can also result in abnormal drug-seeking behavior (addiction/habit-forming). Do not increase your dose, take it more frequently or use it for a longer period of time than prescribed. Properly stop the medication when so directed. This will lessen the chances of becoming addicted.

When used for a long period, this medication may not work as well and may require different dosing. Talk with your doctor if this medication stops working well.

If you are using this drug for ADHD, your doctor may recommend "drug holidays" when the medication is stopped for a short time to observe any changes in behavior.

Inform your doctor if your condition does not improve or if it worsens.

SIDE EFFECTS

Loss of appetite, weight loss, dry mouth, stomach upset/pain, nausea/vomiting, dizziness, headache, diarrhea, fever, nervousness, and trouble sleeping may occur. If any of these effects persist or worsen, notify your doctor promptly.

Remember that your doctor has prescribed this medication because he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects.

Tell your doctor immediately if any of these unlikely but serious side effects occur: mental/mood/behavior changes (e.g., agitation, aggression, mood swings, depression, abnormal thoughts), uncontrolled movements, continuous chewing movements/teeth grinding, outbursts of words/sounds, change in sexual ability/desire.

Seek immediate medical attention if any of these rare but very serious side effects occur: shortness of breath, chest pain, fainting, severe headache, fast/pounding/irregular heartbeat, jaw/left arm pain, seizures, swelling of the ankles/feet, extreme tiredness, blurred vision, weakness on one side of the body, slurred speech, confusion.

A very serious allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of a serious allergic reaction may include: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist.

In the US -

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

In Canada - Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1 -866-234-2345.

PRECAUTIONS:

Before taking this medication, tell your doctor or pharmacist if you are allergic to it; or to sympathomimetic drugs (e.g., epinephrine, pseudoephedrine); or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details.

This medication should not be used if you have certain medical conditions. Before using this medicine, consult your doctor or pharmacist if you have: certain mental/mood conditions (e.g., agitation, psychosis), heart/blood vessel disease (e.g., irregular heartbeat, coronary artery disease, angina, heart failure, cardiomyopathy), problems with heart structure (e.g., valve problems), history of heart attack or stroke, moderate or severe high blood pressure (hypertension), overactive thyroid (hyperthyroidism), a certain eye problem (glaucoma), personal or family history of regular use/abuse of drugs/alcohol.

Before using this medication, tell your doctor or pharmacist your medical history, especially of: personal or family history of uncontrolled movements or outbursts of words/sounds (e.g., due to Tourette's syndrome), family history of sudden death/irregular heartbeat/rhythm, mild high blood pressure (hypertension), kidney disease, liver disease, family/personal history of mental/mood disorders (e.g., bipolar disorder, depression, psychotic disorder, suicidal thoughts), seizures.

This drug may make you dizzy. Do not drive, use machinery, or do any activity that requires alertness until you are sure you can perform such activities safely. Limit alcoholic beverages.

Before having surgery, tell your doctor or dentist that you are taking this medication.

Caution is advised when using this drug in children because it may affect weight, growth rate, and final height. The doctor may recommend temporarily stopping the medication from time to time to avoid this risk. Consult your doctor or pharmacist for more details. This drug is not recommended for use in children under 3.

This medication should be used only when clearly needed during pregnancy. Infants born to mothers dependent on this medication may have birth defects, be born too soon (premature delivery), and have low birth weight. They may also have withdrawal symptoms. Tell your doctor immediately if you notice possible mood changes, agitation, or unusual tiredness in your newborn. Discuss the risks and benefits with your doctor.

This medication passes into breast milk and may have undesirable effects on a nursing infant. Breast-feeding is not recommended while using this drug. Consult your doctor before breast-feeding.

DRUG INTERACTIONS:

Your healthcare professionals (e.g., doctor or pharmacist) may already be aware of any possible drug interactions and may be monitoring you for it. Do not start, stop or change the dosage of any medicine before checking with them first.

This drug should not be used with the following medications because very serious interactions may occur: MAO inhibitors.

Avoid taking MAO inhibitors (isocarboxazid, linezolid, methylene blue, moclobemide, phenelzine, procarbazine, rasagiline, selegiline, tranylcypromine) within 2 weeks before, during, and after treatment with this medication. In some cases, a serious, possibly fatal drug interaction may occur.

If you are currently using any of these medications listed above, tell your doctor or pharmacist before starting this medication.

Before using this medication, tell your doctor or pharmacist of all prescription and nonprescription/herbal products you may use, especially of: certain antidepressants (e.g., tricyclic antidepressants such as nortriptyline and imipramine, SSRIs such as fluoxetine and paroxetine, and SSNRIs such as venlafaxine), alpha blockers (e.g., prazosin), certain antihistamines (e.g., diphenhydramine), beta blockers (e.g., atenolol, metoprolol), drugs for high blood pressure (e.g., clonidine, guanabenz, methyldopa), certain drugs for mental/mood conditions (e.g., antipsychotics such as chlorpromazine/haloperidol, lithium), certain pain medicines (e.g., meperidine, propoxyphene), certain anti-seizure drugs (e.g., ethosuximide, phenytoin, phenobarbital), stimulants (e.g., norepinephrine, phenylephrine), veratrum alkaloids (e.g., cevadine, veratridine).

Certain foods and drugs can affect the amount of acid in your stomach/intestines or urine. This can affect how well your body absorbs and uses this medication. Tell your doctor if you take any of these products: ammonium chloride, antacids, anti-ulcer medicine (e.g., H2 blockers such as famotidine and ranitidine, proton pump inhibitors such as omeprazole and lansoprazole), ascorbic acid (vitamin C), aspirin, carbonic anhydrase inhibitors (e.g., acetazolamide), fruit juices, glutamic acid, guanethidine, methenamine, reserpine, sodium acid phosphate, sodium bicarbonate, certain "water pills" (diuretics, including some thiazides).

If your doctor has directed you to take low-dose aspirin for heart attack or stroke prevention (usually at dosages of 81 -325 milligrams a day), you should continue taking it unless your doctor instructs you otherwise. Ask your doctor or pharmacist for more details.

Also report the use of drugs which might increase seizure risk (decrease seizure threshold) when combined with this medication such as bupropion, isoniazid (INH), phenothiazines (e.g., thioridazine), theophylline, tramadol, or tricyclic antidepressants (e.g., amitriptyline), among others. Consult your doctor or pharmacist for details.

Check the labels on all your medicines (e.g., cough-and-cold products, diet aids) because they may contain ingredients that could increase your heart rate or blood pressure. Ask your pharmacist about the safe use of these products.

Avoid drinking large amounts of beverages containing caffeine (e.g., coffee, tea, colas) or eating large amounts of chocolate. Caffeine can increase the side effects of this medication.

This medication may affect the results of certain lab tests (blood and urine steroid levels). Tell your doctor or laboratory personnel if you are taking this medication.

This document does not contain all possible interactions. Therefore, before using this product, tell your doctor or pharmacist of all the products you use. Keep a list of all your medications with you, and share the list with your doctor and pharmacist.

OVERDOSE:

If overdose is suspected, contact your local poison control center or emergency room immediately. US residents can call the US national poison hotline at 1-800-222-1222. Canadian residents should call their local poison control center directly. Symptoms of overdose may include: severe mental/mood changes, seizures, severe or persistent headache, severe restlessness, fast breathing.

NOTES:

Do not share this medication with others. It is against the law.

Laboratory and/or medical tests (e.g., blood pressure, heart rate, growth monitoring in children) may be performed to check for side effects. Consult your doctor for more details.

MISSED DOSE:

If you miss a dose, use it as soon as you remember in the morning hours. If it is less than 6 hours until bedtime, or if it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

STORAGE:

Store at room temperature at 77 degrees F (25 degrees C) in a tightly closed container. Brief storage between 59-86 degrees F (15-30 degrees C) is permitted. Do not store in the bathroom. Protect from light and moisture. Keep all medicines away from children and pets.

Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company for more details about how to safely discard your product.

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