

AMPHETAMINES HAVE A HIGH POTENTIAL FOR ABUSE. ADMINISTRATION OF AMPHETAMINES FOR PROLONGED PERIODS OF TIME MAY LEAD TO DRUG DEPENDENCE AND MUST BE AVOIDED. PARTICULAR ATTENTION SHOULD BE PAID TO THE POSSIBILITY OF SUBJECTS RETAINING AMPHETAMINES FOR NON-THERAPEUTIC USE OR DISTRIBUTION TO OTHERS, AND THE DRUGS SHOULD BE PRESCRIBED OR DISPENSED SPARINGLY. MISUSE OF AMPHETAMINE MAY CAUSE SUDDEN DEATH AND SERIOUS CARDIOVASCULAR ADVERSE EVENTS.

DESCRIPTION								
A single-entity amphetamine product combining the neutral sulfate salts of dextroamphetamine and amphetamine, with the dextro isomer of amphetamine saccharate and D-Isosame amphetamine Aspartate. (Anhydrous) as supplied								
EACH TABLET CONTAINS	5 mg	7.5 mg	10 mg	12.5 mg	15 mg	20 mg	30 mg	
Dextroamphetamine Saccharate	1.25 mg	1.875 mg	2.5 mg	3.125 mg	3.75 mg	5 mg	7.5 mg	
Amphetamine Aspartate Monohydrate Equivalent	1.25 mg ^a	1.875 mg ^b	2.5 mg ^c	3.125 mg ^d	3.75 mg ^e	5 mg ^f	7.5 mg ^g	
Dextroamphetamine Sulfate, USP	1.25 mg	1.875 mg	2.5 mg	3.125 mg	3.75 mg	5 mg	7.5 mg	
Amphetamine Sulfate, USP	1.25 mg	1.875 mg	2.5 mg	3.125 mg	3.75 mg	5 mg	7.5 mg	
Total Amphetamine Base Equivalence	3.13 mg	4.7 mg	6.3 mg	7.8 mg	9.4 mg	12.6 mg	18.8 mg	
a 1.25 mg of Amphetamine Aspartate Monohydrate equivalent to 1.17 mg Amphetamine Aspartate (Anhydrous) as supplied								
b 1.875 mg of Amphetamine Aspartate Monohydrate equivalent to 1.755 mg Amphetamine Aspartate (Anhydrous) as supplied								
c 2.5 mg of Amphetamine Aspartate Monohydrate equivalent to 2.34 mg Amphetamine Aspartate (Anhydrous) as supplied								
d 3.125 mg of Amphetamine Aspartate Monohydrate equivalent to 2.925 mg Amphetamine Aspartate (Anhydrous) as supplied								
e 3.75 mg of Amphetamine Aspartate Monohydrate equivalent to 3.51 mg Amphetamine Aspartate (Anhydrous) as supplied								
f 5 mg of Amphetamine Aspartate Monohydrate equivalent to 4.6 mg Amphetamine Aspartate (Anhydrous) as supplied								
g 7.5 mg of Amphetamine Aspartate Monohydrate equivalent to 7.03 mg Amphetamine Aspartate (Anhydrous) as supplied								

Inactive Ingredients: colloidal silicon dioxide, compressible sugar, corn starch, magnesium stearate, microcrystalline cellulose and saccharin sodium.

Colors: Adderal® 5 mg is a white to off-white tablet, which contains no color additives. Adderal® 7.5 mg and 10 mg contain F&B Blue #1 Aluminum Lake as a color additive. Adderal® 12.5 mg, 15 mg, 20 mg and 30 mg contain F&B Yellow #6 Aluminum Lake as a color additive.

CLINICAL PHARMACOLOGY

Pharmacodynamics

Amphetamines are non-catecholamine sympathomimetic amines with CNS stimulant activity. The mode of therapeutic action in Attention Deficit Hyperactivity Disorder (ADHD) is not known. Amphetamines are thought to block the reuptake of norepinephrine and dopamine into the presynaptic neuron and increase the release of these monoamines into the extraneuronal space.

Pharmacokinetics

Adderal® tablets contain d-amphetamines and l-amphetamine salts in the ratio of 3:1. Following administration of a single dose of 10 or 30 mg of Adderal® to healthy volunteers under fasted conditions, peak plasma concentrations occurred approximately 3 hours post-dose for both d-amphetamine and l-amphetamine. The mean elimination half-life ($t_{1/2}$) for d-amphetamine was shorter than the $t_{1/2}$ of l-isomer (8.77 hr vs. 11.5 to 13.8 hours). The PK parameters (C_{max} , $AUC_{0-\infty}$) of d- and l-amphetamine increased approximately three-fold from 10 mg to 30 mg indicating dose-proportional pharmacokinetics.

The effect of food on the bioavailability of Adderal® has not been studied.

Metabolism and Excretion
Amphetamine is reported to be oxidized at the 4-position of the benzene ring to form 4-hydroxyamphetamine, or on the side chain α or β carbons to form alpha-hydroxy-amphetamine or norephedrine, respectively. Norephedrine and 4-hydroxy-amphetamine are both active and each is subsequently oxidized to form 4-hydroxy-norephedrine. Alpha-hydroxy-amphetamine undergoes deamination to form phenylethylamine which ultimately forms benzoic acid and its glucuronide and the glycine conjugate hippuric acid. Although the enzymes involved in amphetamine metabolism have not been clearly defined, CYP2D6 is known to be involved with formation of 4-hydroxy-amphetamine. Since CYP2D6 is genetically polymorphic, population variations in amphetamine metabolism are a possibility.

Amphetamine is known to inhibit monoamine oxidase, whereas the ability of amphetamine and its metabolites to inhibit various P450 isozymes and other enzymes has not been adequately elucidated. *In vitro* experiments with human microsomes indicate minor inhibition of CYP2D6 by amphetamine and minor inhibition of CYP1A2, C2D6, and 3A4 by one or more metabolites. However, due to the probability of auto-inhibition and the lack of information on the concentration of these metabolites relative to *in vivo* concentrations, no prediction can be made as to the potential for amphetamine or its metabolites to inhibit the metabolism of other drugs by CYP isozymes *in vivo* can be made.

With normal urine pHs approximately half of an administered dose of amphetamine is recoverable in urine as derivatives of alpha-hydroxy-amphetamine and approximately another 30% to 40% of the dose is recoverable in urine as amphetamine, norephedrine, and 4-hydroxy-amphetamine. Amphetamine is highly dependent on pH and urine flow rates. Alkaline urine pHs result in less ionization and reduced renal elimination, and acidic pHs and high flow rates result in increased renal elimination with clearances greater than glomerular filtration rates, indicating the involvement of active secretion. Urinary recovery of amphetamine has been reported to range from 15% to 75%, depending on urinary pH, with the remaining fraction of the dose hepatically metabolized. Consequently, both hepatic and renal dysfunction have the potential to inhibit the elimination of amphetamine and result in prolonged exposures. In addition, drugs that affect urinary pH are known to alter the elimination of amphetamine, and any decrease in amphetamine's metabolism that might occur due to drug interactions or genetic polymorphisms is more likely to be clinically significant when renal elimination is decreased (see **PRECAUTIONS**).

INDICATIONS AND USAGE

Adderal® is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) and Narcolepsy.

Attention Deficit Hyperactivity Disorder (ADHD)

A diagnosis of Attention Deficit Hyperactivity Disorder (ADHD; DSM-IV®) implies the presence of hyperactive-impulsive or inattentive symptoms that caused impairment and were present before age 7 years. The symptoms must cause clinically significant impairment, e.g., in social, academic, or occupational functioning, and be present in two or more settings, e.g., school (or work) and at home. The symptoms must not be better accounted for by another mental disorder. For the inattentive type, at least six of the following symptoms must have persisted for at least 6 months and have caused details/characteristics: inattention; makes mistakes; lack of sustained attention; poor listener; failure to follow through on tasks; poor organization; avoids tasks requiring sustained mental effort; loses things; easily distracted; forgetful. For the hyperactive-impulsive type, at least six of the following symptoms must have persisted for at least 6 months: fidgeting/squirming; leaving seat; inappropriate running/climbing; difficulty with quiet activities; "on the go," excessive talking; blurt answers; can't wait turn; intrusive. The Combined type requires both inattentive and hyperactive-impulsive criteria to be met.

Specific Diagnostic Considerations
Specific etiology of this syndrome is unknown, and there is no single diagnostic test. Adequate diagnosis requires the use not only of medical but of special psychological, educational, and social resources. Learning may or may not be impaired. The diagnosis must be based upon a complete history and evaluation of the child and not solely on the presence of the required number of DSM-IV® characteristics.

Need for Comprehensive Treatment Program

Adderal® is indicated as an integral part of a total treatment program for ADHD that may include other measures (psychological, educational, social) for patients with this syndrome. Drug treatment may not be indicated for all children with this syndrome. Stimulants are not intended for use in the child who exhibits symptoms secondary to environmental factors and/or other primary psychiatric disorders, including psychosis. Appropriate educational and psychological intervention and other helpful When remedial measures alone are insufficient, the decision to prescribe stimulant medication will depend upon the physician's assessment of the chronicity and severity of the child's symptoms.

Long-Term Use

The effectiveness of Adderal® for long-term use has not been systematically evaluated in controlled trials. Therefore, the physician who elects to use Adderal® for extended periods should periodically re-evaluate the long-term usefulness of the drug for the individual patient.

CONTRAINDICATIONS

Advanced atherosclerosis, symptomatic cardiovascular disease, moderate to severe hypertension, hyperthyroidism, known hypersensitivity or idiosyncrasy to the sympathomimetic amines, glaucoma. Agitated states.

Patients with a history of drug abuse.

During or within 14 days following the administration of monoamine oxidase inhibitors (hypertensive crises may result).

WARNINGS

Serious Cardiovascular Events

Sudden Death and Preexisting Structural Cardiac Abnormalities or Other Serious Heart Problems
Children and Adolescents
Sudden death has been reported in association with CNS stimulant treatment at usual doses in children and adolescents with structural cardiac abnormalities or other serious heart conditions. Although some structural heart problems alone may carry an increased risk of sudden death, stimulant products generally should not be used in children or adolescents with known structural cardiac abnormalities, cardiomyopathy, serious heart rhythm abnormalities, or other serious cardiac problems that may place them at increased vulnerability to the sympathomimetic effects of a stimulant drug (see **CONTRAINDICATIONS**).

Adults

Sudden deaths, stroke, and myocardial infarction have been reported in adults taking stimulant drugs at usual doses for ADHD. Although the role of stimulants in these adult cases is also unknown, adults have a greater likelihood than children of structural cardiac abnormalities, cardiomyopathy, serious heart rhythm abnormalities, coronary artery disease, or other serious cardiac problems. Adults with such abnormalities should also generally not be treated with stimulant drugs (see **CONTRAINDICATIONS**).

Hypertension and Other Cardiovascular Conditions

Stimulant medications cause a modest increase in average blood pressure (about 2 to 4 mmHg) and average heart rate (about 3 to 6 bpm) (see **ADVERSE REACTIONS**), and individuals may have larger increases. While the mean changes alone would not be expected to have short-term consequences, all patients should be monitored for larger changes in heart rate and blood pressure. Caution is indicated in treating patients whose underlying medical conditions might be compromised by increases in blood pressure or heart rate, e.g., those with preexisting hypertension, heart failure, recent myocardial infarction, or ventricular arrhythmia (see **CONTRAINDICATIONS**).

Assessing Cardiovascular Status in Patients Being Treated With Stimulant Medications

Children, adolescents, or adults who are being considered for treatment with stimulant medications should have a careful history (including assessment for a family history of sudden death or ventricular arrhythmia) and physical exam to assess for the presence of cardiac disease, and should receive further cardiac evaluation if findings suggest such disease (e.g., electrocardiogram and echocardiogram). Patients who develop symptoms such as exertional chest pain, unexplained syncope, or other symptoms suggestive of cardiac disease during stimulant treatment should undergo a prompt cardiac evaluation.

Psychiatric Adverse Events

Preexisting Psychosis

Amphetamines may exacerbate symptoms of behavior disturbance and thought disorder in patients with preexisting psychotic disorder.

Bipolar Illness

Particular care should be taken in using stimulants to treat ADHD in patients with comorbid bipolar disorder because of concern for possible induction of mixed/manic episode in such patients. Prior to initiating treatment with a stimulant, patients with comorbid depressive symptoms should be adequately screened to determine if they are at risk for bipolar disorder, such screening should include a detailed psychiatric history, including a family history of suicide, bipolar disorder, and depression.

Emergence of New Psychotic or Manic Symptoms

Treatment emergent psychotic or manic symptoms, e.g., hallucinations, delusional thinking, or mania in children and adolescents without prior history of psychotic illness or mania can be caused by stimulant treatment. Such symptoms should be considered as potentially a possible causal result of the stimulant, and discontinuation of treatment may be appropriate. In a pooled analysis of multiple short-term, placebo-controlled studies, such symptoms occurred in about 0.1% (4 patients) with events out of 2482 exposed to methylphenidate or amphetamine for several weeks at usual doses) of stimulant-treated patients compared to 0 in placebo-treated patients.

Aggression

Aggressive behavior or hostility is often observed in children and adolescents with ADHD, and has been reported in clinical trials and the postmarketing experience of some medications indicated for the treatment of ADHD. Although there is no systematic evidence that stimulants cause aggressive behavior or hostility, patients beginning treatment for ADHD should be monitored for the appearance or worsening of aggressive behavior or hostility.

Long-Term Suppression of Growth

Long-term effects of weight and height in children ages 7 to 10 years who were randomized to either methylphenidate or non-medication treatment groups over 14 months, as well as in naturalistic subgroups of newly methylphenidate-treated and non-medication treated children over 36 months (to the ages of 10 to 13 years), suggests that consistently medicated children (i.e., treatment for 7 days per week throughout the year) have a temporary slowing in growth rate (on average, a total of about 2 cm less growth in height and 2.7 kg less growth in weight over 3 years), without evidence of growth rebound during this period of development. Published data are inadequate to determine whether chronic use of amphetamines may cause a similar suppression of growth, however, it is anticipated that they will likely have the effect of the stimulants. Caution should be exercised during treatment with amphetamines and patients who are growing or gaining weight as expected may need to have their treatment interrupted.

Seizures

There is some clinical evidence that stimulants may lower the convulsive threshold in patients with prior history of seizure, in patients with prior EEG abnormalities in absence of seizure, and very rarely, in patients without a history of seizures and no prior EEG evidence of seizures. In the presence of seizures, the drug should be discontinued.

Visual Disturbances

Difficulty with accommodation and blurring of vision have been reported with stimulant treatment.

PRECAUTIONS

General

The least amount of amphetamine feasible should be prescribed or dispensed at one time in order to minimize the possibility of overdose. Adderal® should be used with caution in patients who use other sympathomimetic drugs.

Tics

Amphetamines have been reported to exacerbate motor and phonic tics and Tourette's syndrome. Therefore, clinical evaluation for tics and Tourette's syndrome in children and their families should precede use of stimulant medications.

Information for Patients

Amphetamines may impair the ability of the patient to engage in potentially hazardous activities such as operating machinery or vehicles; the patient should therefore be cautioned accordingly.

Prescribers or other health professionals should inform patients, their families, and their caregivers about the benefits and risks associated with treatment with amphetamine or dextroamphetamine and should counsel them that amphetamine or dextroamphetamine is available for abuse.

The prescriber or health professional should instruct patients, their families, and their caregivers to read the Medication Guide and should assist them in understanding its contents. Patients should be given the opportunity to discuss the contents of the Medication Guide and to obtain answers to any questions they may have. The complete text of the Medication Guide is reprinted at the end of this document.

Drug Interactions

Acidifying Agents

Gastrointestinal acidifying agents (guanethidine, reserpine, glutamic acid HCl, ascorbic acid, fruit juices, etc.) lower blood levels and effects of amphetamines.

Urinary Alkalinizing Agents

(ammonium chloride, sodium acid phosphate, etc.) increase the concentration of the ionized species of the amphetamine molecule, thereby increasing urinary excretion. Both groups of agents lower blood levels and effects of amphetamines.

Adrenergic Blockers

Adrenergic blockers are inhibited by amphetamines.

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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 Adderall® without talking to your doctor first.

How should Adderall® be taken?

- **Take Adderall® exactly as prescribed.** Your doctor may adjust the dose until it is right for you or your child.

- Adderall® tablets 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.

- Adderall® can be taken with or without food.

- From time to time, your doctor may stop Adderall® treatment for a while to check ADHD symptoms.
- Your doctor may do regular checks of the blood, heart, and blood pressure while taking Adderall®. Children should have their height and weight checked often while taking Adderall®. Adderall® treatment may be stopped if a problem is found during these check-ups.

- **If you or your child take too much Adderall® or overdoses, call your doctor or poison control center right away, or get emergency treatment.**

What are possible side effects of Adderall®?

See “**What is the most important information I should know about Adderall®?**” 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
- stomach ache
- trouble sleeping
- decreased appetite
- nervousness
- dizziness

Adderall® may affect your 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.

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 Adderall®?

- Store Adderall® in a safe place at room temperature, 20° to 25°C (68° to 77°F).

- **Keep Adderall® and all medicines out of the reach of children.**

General information about Adderall®
Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Adderall® for a condition for which it was not prescribed. Do not give Adderall® 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 Adderall®. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about Adderall® that was written for healthcare professionals. For more information about Adderall®, please contact Teva Pharmaceuticals at 1-888-838-2872.

What are the ingredients in Adderall®? Active Ingredient: dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate.

Inactive Ingredients: colloidal silicon dioxide, compressible sugar, corn starch, magnesium stearate, microcrystalline cellulose and saccharin sodium. The 5 mg is a white to off-white tablet, which contains no color additives. The 7.5 mg and 10 mg also contain FD&C Blue #1 Aluminum Lake as a color additive. The 12.5 mg, 15 mg, 20 mg and 30 mg also contain FD&C Yellow #6 Aluminum Lake as a color additive.

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

TEVA PHARMACEUTICALS USA
Sellersville, PA 18960

Rev. C 6/2013

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Inactive Ingredients: colloidal silicon dioxide, compressible sugar, corn starch, magnesium stearate, microcrystalline cellulose and saccharin sodium. The 5 mg is a white to off-white tablet, which contains no color additives. The 7.5 mg and 10 mg also contain FD&C Blue #1 Aluminum Lake as a color additive. The 12.5 mg, 15 mg, 20 mg and 30 mg also contain FD&C Yellow #6 Aluminum Lake as a color additive.

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

TEVA PHARMACEUTICALS USA
Sellersville, PA 18960

Rev. C 6/2013

This label was last approved by FDA.

For current labeling information, please visit <https://www.fda.gov/drugsatfda>

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 Adderall® without talking to your doctor first.

How should Adderall® be taken?

- **Take Adderall® exactly as prescribed.** Your doctor may adjust the dose until it is right for you or your child.

- Adderall® tablets 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.

- Adderall® can be taken with or without food.

- From time to time, your doctor may stop Adderall® treatment for a while to check ADHD symptoms.
- Your doctor may do regular checks of the blood, heart, and blood pressure while taking Adderall®. Children should have their height and weight checked often while taking Adderall®. Adderall® treatment may be stopped if a problem is found during these check-ups.

- **If you or your child take too much Adderall® or overdoses, call your doctor or poison control center right away, or get emergency treatment.**

What are possible side effects of Adderall®?

See “**What is the most important information I should know about Adderall®?**” 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
- stomach ache
- trouble sleeping
- decreased appetite
- nervousness
- dizziness

Adderall® may affect your 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.

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 Adderall®?

- Store Adderall® in a safe place at room temperature, 20° to 25°C (68° to 77°F).

- **Keep Adderall® and all medicines out of the reach of children.**

General information about Adderall®
Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Adderall® for a condition for which it was not prescribed. Do not give Adderall® 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 Adderall®. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about Adderall® that was written for healthcare professionals. For more information about Adderall®, please contact Teva Pharmaceuticals at 1-888-838-2872.

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Inactive Ingredients: colloidal silicon dioxide, compressible sugar, corn starch, magnesium stearate, microcrystalline cellulose and saccharin sodium. The 5 mg is a white to off-white tablet, which contains no color additives. The 7.5 mg and 10 mg also contain FD&C Blue #1 Aluminum Lake as a color additive. The 12.5 mg, 15 mg, 20 mg and 30 mg also contain FD&C Yellow #6 Aluminum Lake as a color additive.

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TEVA PHARMACEUTICALS USA
Sellersville, PA 18960

Rev. C 6/2013

MEDICATION GUIDE
Adderall® (*ADD-ur-all*)
(Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate and Amphetamine Sulfate Tablets)

Read only

Read the Medication Guide that comes with Adderall® 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 Adderall®.

What is the most important information I should know about Adderall®?
The following have been reported with use of Adderall® 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 Adderall®.

Your doctor should check your or your child's blood pressure and heart rate regularly during treatment with Adderall®.

Call your doctor right away if you or your child have any signs of heart problems such as chest pain, shortness of breath, or fainting while taking Adderall®.

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**
- **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 Adderall®, especially seeing or hearing things that are not real, believing things that are not real, or are suspicious.

What is Adderall®?

Adderall® is a central nervous system stimulant prescription medicine. **It is used for the treatment of Attention-Deficit Hyperactivity Disorder (ADHD).** Adderall® may help increase attention and decrease impulsiveness and hyperactivity in patients with ADHD.

Adderall® should be used as a part of a total treatment program for ADHD that may include counseling or other therapies.

Adderall® is also used in the treatment of a sleep disorder called narcolepsy.

Adderall® is a federally controlled substance (CII) because it can be abused or lead to dependence. Keep Adderall® in a safe place to prevent misuse and abuse. Selling or giving away Adderall® 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 Adderall®?

Adderall® 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

Adderall® is not recommended for use in children less than 3 years old.

Adderall® may not be right for you or your child. Before starting Adderall® 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
- 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 Adderall® 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. Adderall® 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 Adderall®.

Your doctor will decide whether Adderall® 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 Adderall® without talking to your doctor first.

How should Adderall® be taken?

- **Take Adderall® exactly as prescribed.** Your doctor may adjust the dose until it is right for you or your child.

- Adderall® tablets 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.

- Adderall® can be taken with or without food.
- From time to time, your doctor may stop Adderall® treatment for a while to check ADHD symptoms.

- Your doctor may do regular checks of the blood, heart, and blood pressure while taking Adderall®. Children should have their height and weight checked often while taking Adderall®. Adderall® treatment may be stopped if a problem is found during these check-ups.

- **If you or your child take too much Adderall® or overdoses, call your doctor or poison control center right away, or get emergency treatment.**

What are possible side effects of Adderall®?

See “**What is the most important information I should know about Adderall®?**” 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
- stomach ache
- trouble sleeping
- decreased appetite
- nervousness
- dizziness

Adderall® may affect your 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.

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 Adderall®?

- Store Adderall® in a safe place at room temperature, 20° to 25°C (68° to 77°F).

- **Keep Adderall® and all medicines out of the reach of children.**

General information about Adderall®

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Adderall® for a condition for which it was not prescribed. Do not give Adderall® 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 Adderall®. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about Adderall® that was written for healthcare professionals. For more information about Adderall®, please contact Teva Pharmaceuticals at 1-888-838-2872.

What are the ingredients in Adderall®?

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Sellersville, PA 18960

Rev. C 6/2013

MEDICATION GUIDE

Adderall® (ADD-ur-all)

(Dextroamphetamine Saccharate,
Amphetamine Aspartate,
Dextroamphetamine Sulfate and
Amphetamine Sulfate Tablets)

R only

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What is the most important information I should know about Adderall®?

The following have been reported with use of Adderall® 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 Adderall®.

Your doctor should check your or your child's blood pressure and heart rate regularly during treatment with Adderall®.

Call your doctor right away if you or your child have any signs of heart problems such as chest pain, shortness of breath, or fainting while taking Adderall®.

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 Adderall®, especially seeing or hearing things that are not real, believing things that are not real, or are suspicious.

What is Adderall®?

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Adderall® should be used as a part of a total treatment program for ADHD that may include counseling or other therapies.

Adderall® is also used in the treatment of a sleep disorder called narcolepsy.

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Adderall® should not be taken if you or your child:

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- 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

Adderall® is not recommended for use in children less than 3 years old.

Adderall® may not be right for you or your child. Before starting Adderall® 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
- 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 Adderall® 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. Adderall® 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 Adderall®.

Your doctor will decide whether Adderall® 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 Adderall® without talking to your doctor first.

How should Adderall® be taken?

- **Take Adderall® exactly as prescribed.** Your doctor may adjust the dose until it is right for you or your child.
- Adderall® tablets 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.
- Adderall® can be taken with or without food.
- From time to time, your doctor may stop Adderall® treatment for a while to check ADHD symptoms.
- Your doctor may do regular checks of the blood, heart, and blood pressure while taking Adderall®. Children should have their height and weight checked often while taking Adderall®. Adderall® treatment may be stopped if a problem is found during these check-ups.
- **If you or your child take too much Adderall® or overdoses, call your doctor or poison control center right away, or get emergency treatment.**

What are possible side effects of Adderall®?

See “What is the most important information I should know about Adderall®?” 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
- stomach ache
- trouble sleeping
- decreased appetite
- nervousness
- dizziness

Adderall® may affect your 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.

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 Adderall®?

- Store Adderall® in a safe place at room temperature, 20° to 25°C (68° to 77°F).
- **Keep Adderall® and all medicines out of the reach of children.**

General information about Adderall®

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What are the ingredients in Adderall®?

Active Ingredient: dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate.

Inactive Ingredients: colloidal silicon dioxide, compressible sugar, corn starch, magnesium stearate, microcrystalline cellulose and saccharin sodium. The 5 mg is a white to off-white tablet, which contains no color additives. The 7.5 mg and 10 mg also contain FD&C Blue #1 Aluminum Lake as a color additive. The 12.5 mg, 15 mg, 20 mg and 30 mg also contain FD&C Yellow #6 Aluminum Lake as a color additive.

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Sellersville, PA 18960

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amphetamineaspartate, dextroamphetaminesulfate and 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 while taking dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets.

Your doctor will decide whether dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets 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 dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets without talking to your doctor first.

How should dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets be taken?

- **Take dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets exactly as prescribed.** Your doctor may adjust the dose until it is right for you or your child.
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- Dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets can be taken with or without food.
- From time to time, your doctor may stop dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets treatment for a while to check ADHD symptoms.
- Your doctor may do regular checks of the blood, heart, and blood pressure while taking dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets. Children should have their height and weight checked often while taking dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets. Dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets treatment may be stopped if a problem is found during these check-ups.

- **If you or your child take too much dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets or overdoses, call your doctor or poison control center right away, or get emergency treatment.**

What are possible side effects of dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets?

See “What is the most important information I should know about dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets?” 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
- stomach ache
- trouble sleeping
- decreased appetite
- nervousness
- dizziness

Dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets may affect your 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 dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets?

- Store dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets in a safe place at room temperature, 20° to 25°C (68° to 77°F).
- **Keep dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets and all medicines out of the reach of children.**

General information about dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets for a condition for which it was not prescribed. Do not give dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets 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 dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets that was written for healthcare professionals. For additional information on dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets, please contact Teva Pharmaceuticals at 1-888-838-2872.

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

What are the ingredients in dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets?

Active Ingredients: dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate.

Inactive Ingredients: colloidal silicon dioxide, compressible sugar, corn starch, magnesium stearate, microcrystalline cellulose and saccharin sodium. The 5 mg, 7.5 mg and 10 mg also contain FD&C Blue #1 Aluminum Lake. The 12.5 mg, 15 mg, 20 mg and 30 mg also contain FD&C Yellow #6 Aluminum Lake. KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

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✂ amphetamineaspartate, dextroamphetaminesulfate and 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 while taking dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets.

Your doctor will decide whether dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets 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 dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets without talking to your doctor first.

How should dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets be taken?

- **Take dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets exactly as prescribed.** Your doctor may adjust the dose until it is right for you or your child.
- Dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets 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.
- Dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets can be taken with or without food.
- From time to time, your doctor may stop dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets treatment for a while to check ADHD symptoms.
- Your doctor may do regular checks of the blood, heart, and blood pressure while taking dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets. Children should have their height and weight checked often while taking dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets. Dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets treatment may be stopped if a problem is found during these check-ups.

- **If you or your child take too much dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets or overdoses, call your doctor or poison control center right away, or get emergency treatment.**

What are possible side effects of dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets?

See “What is the most important information I should know about dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets?” 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
- stomach ache
- trouble sleeping
- decreased appetite
- nervousness
- dizziness

Dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets may affect your 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 dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets?

- Store dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets in a safe place at room temperature, 20° to 25°C (68° to 77°F).

- **Keep dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets and all medicines out of the reach of children.**

General information about dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets.

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What are the ingredients in dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets?

Active Ingredients: dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate.

Inactive Ingredients: colloidal silicon dioxide, compressible sugar, corn starch, magnesium stearate, microcrystalline cellulose and saccharin sodium. The 5 mg, 7.5 mg and 10 mg also contain FD&C Blue #1 Aluminum Lake. The 12.5 mg, 15 mg, 20 mg and 30 mg also contain FD&C Yellow #6 Aluminum Lake.

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.

TEVA PHARMACEUTICALS USA
Sellersville, PA 18960

Rev. C 6/2013

MEDICATION GUIDE

DEXTROAMPHETAMINE SACCHARATE, AMPHETAMINE ASPARTATE, DEXTROAMPHETAMINE SULFATE AND AMPHETAMINE SULFATE



(DEX-troe-am-FET-uh-meen SACK-uh-rate,
am-FET-uh-meen ass-PAR-tate,
DEX-troe-am-FET-uh-meen SULL-fate,
and am-FET-uh-meen SULL-fate)

TABLETS

Rx only

Read the Medication Guide that comes with dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets 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 dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets.

What is the most important information I should know about dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets?

The following have been reported with use of dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets 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 dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets.

Your doctor should check your or your child's blood pressure and heart rate regularly during treatment with dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets.

Call your doctor right away if you or your child have any signs of heart problems such as chest pain, shortness of breath, or fainting while taking dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets.

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 dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets, especially seeing or hearing things that are not real, believing things that are not real, or are suspicious.

What are dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets?

Dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets are a central nervous

system stimulant prescription medicine. It is used for the treatment of Attention-Deficit Hyperactivity Disorder (ADHD). Dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets may help increase attention and decrease impulsiveness and hyperactivity in patients with ADHD.

Dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets should be used as a part of a total treatment program for ADHD that may include counseling or other therapies.

Dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets are also used in the treatment of a sleep disorder called narcolepsy.

Dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets are a federally controlled substance (CII) because it can be abused or lead to dependence. Keep dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets in a safe place to prevent misuse and abuse. Selling or giving away dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets 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 dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets?

Dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets 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

Dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets are not recommended for use in children less than 3 years old.

Dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets may not be right for you or your child. Before starting dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets 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
- 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 dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets 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. Dextroamphetamine saccharate,

amphetamine aspartate, dextroamphetamine sulfate and 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 while taking dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets.

Your doctor will decide whether dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets 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 dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets without talking to your doctor first.

How should dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets be taken?

- **Take dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets exactly as prescribed.** Your doctor may adjust the dose until it is right for you or your child.
- Dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets 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.
- Dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets can be taken with or without food.
- From time to time, your doctor may stop dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets treatment for a while to check ADHD symptoms.
- Your doctor may do regular checks of the blood, heart, and blood pressure while taking dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets. Children should have their height and weight checked often while taking dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets. Dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets treatment may be stopped if a problem is found during these check-ups.
- **If you or your child take too much dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets or overdoses, call your doctor or poison control center right away, or get emergency treatment.**

What are possible side effects of dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets?

See “What is the most important information I should know about dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets?” 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
- stomach ache
- trouble sleeping
- decreased appetite
- nervousness
- dizziness

Dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets may affect your 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 dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets?

- Store dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets in a safe place at room temperature, 20° to 25°C (68° to 77°F).
- **Keep dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets and all medicines out of the reach of children.**

General information about dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets for a condition for which it was not prescribed. Do not give dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets 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 dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets that was written for healthcare professionals. For additional information on dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets, please contact Teva Pharmaceuticals at 1-888-838-2872.

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

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This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

KOUNG U LEE
09/25/2013
For Wm. Peter Rickman