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 OBTAINING AMPHETAMINES FOR NON-THERAPEUTIC USE OR DISTRIBUTION TO OTHERS, AND

MISUSE OF AMPHETAMINE MAY CAUSE SUDDEN DEATH AND SERIOUS CARDIOVASCULAI ADVERSE EVENTS.

amphetamine, with the dextro isomer of amphetamine saccharate and d, I-amphetamine aspartate.								
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	

ACH TABLET CONTAINS	5 mg	7.5 mg	10 mg	12.5 mg	15 mg	20 mg	30 mg
Dextroamphetamine Baccharate	1.25 mg	1.875 mg	2.5 mg	3.125 mg	3.75 mg	5 mg	7.5 mg
Imphetamine Aspartate Nonohydrate Equivalent	1.25 mga	1.875 mgb	2.5 mgc	3.125 mgd	3.75 mge	5 mgf	7.5 mgg
Dextroamphetamine Sulfate, USP	1.25 mg	1.875 mg	2.5 mg	3.125 mg	3.75 mg	5 mg	7.5 mg
Imphetamine Sulfate, USP	1.25 mg	1.875 mg	2.5 mg	3.125 mg	3.75 mg	5 mg	7.5 mg
otal Amphetamine Base quivalence	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							

- 5 mg of Amphetamine Aspartate Monohydrate equivalent to 4.6 mg Amphetamine Aspartate Only or Amphetamine Asparate without production of the Management of the Management
- Inactive Ingredients: colloidal silicon dioxide, compressible sugar, corn starch, magnesium stearate, microcrystalline cellulose and saccharin sodium.

Colors: Adderall® 5 mg is a white to off-white tablet, which contains no color additives.

CLINICAL PHARMACOLOGY

Pharmacokinetics
Adderall® tablets contain d-amphetamine and l-amphetamine salts in the ratio of 3.1. Following administration of a single dose 10 or 30 mg of Adderall® 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 (f_{1/2}) for d-amphetamine shorter than the f_{1/2} of the 1-isomer (9.77 to 11 hours vs. 11.5 to 13.8 hours). The PK parameters (C_{max}, AUC_{0-inf}) of d-amphetamine increased approximately three-fold from 10 mg to 30 mg additions does proportional harmacokingings. The effect of food on the bioavailability of Adderall® has not been studied.

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.

With normal urine pHs approximately half of an administered dose of amphetamine is recoverable in 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 itself. Since amphetamine has a pKs of 9.9, urinary recovery of 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 1% 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 after the elimination of amphetamine, and any decrease in amphetamines, metabolism that might occur due to drug interactions or genefic polymorphisms is more

Adderall® 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: lack of attention to details/careless 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: flogeting/sugniming; leaving seat; inappropriate running/clining; difficulty with quiet activities; "on the go?" excessive talking; blurting answers; can't wait turn; intrusive. The Combined Type requires both inattentive and hyperactive-impulsive criteria to be met.

Special Diagnostic Considerations

pecial Diagnostic Considerations
pecific etiology of this syndrome is unknown, and there is no single diagnostic test. Adequate diagnosis

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

vperthyroidism, known hypersensitivity or idiosyncrasy to the sympathomimetic amines, glaucoma

atients with a history of drug abu During or within 14 days following the administration of monoamine oxidase inhibitors (hypertensive

Sudden Death and Preexisting Structural Cardiac Abnormalities or Other Serious Heart Problems

to the sympathomimetic effects of a stimulant drug (see CONTRAINDICATIONS).

eart rhythm abnormalities, coronary artery disease, or other serious cardiac problems. Adults with such bnormalities should also generally not be treated with stimulant drugs (see CONTRAINDICATIONS).

abnormaines should also generally not be treated with stimulant drugs (see CUN HAINDUCATIONS). 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). Amphetamine, in the enantiomer ratio present in Adderall® (immediate-release)(d- to I- ratio of 3:1), was not clastogenic in the mouse bone marrow micronucleus test *in vivo* and vas negative when tested in the E. coli component of the Ames test *in vitro* d, I-Amphetamine (1:1 enantiomer ratio) has been reported to produce a positive response in the mouse bone marrow micronucleus test, an equivocal response in the make test, and negative responses in the *in vitro* sister chromatid exchange and chromosomal aberration assays.

Assessing Cardiovascular Status in ratients being treated with Saturatin 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 findings suggest such disease (e.g., electrocardiogram and echocardiogram). Patients who develop symptoms such as exertional chest pain, unexplained synope, or other symptoms suggestive of cardiac disease during stimulant treatment should undergo a prompt cardiac evaluation.

approximately 1.5 and 8 times, respectively, the maximum recommended human dose of 30 mg/day (child) on a mg/m² body surface area basis. Fetal matiornations and death have been reported in mice following parenteral administration of d-amphetamine doses of 50 mg/kg/day (approximately 6 times that of a human dose of 30 mg/day (child) on a mg/m² basis) or greater to pregnant animals. Administration of these doses was also associated with severe maternal toxicity.

A number of studies in rodents indicate that prenatal or early postnatal exposure to amphetamine (d- or d,l-), at doses similar to those used clinically, can result in long-term neurochemical and behavioral afterations. Reported behavioral effects include learning and memory deficits, altered locomotor activity, and changes in sexual function. history, including a family history of suicide, bipolar disorder, and depression.

nistory, including a tamily nistory of suciode, pipolar 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 stimulants at usual doses. If such symptoms occur, consideration should be given to a possible causal role 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 3482 exposed to methylphenidate or amphetamine for several weeks at usual doses) of stimulant-treated patients compared to 0 in placebo-treated patients.

There are no adequate and well-controlled studies in pregnant women. There has been one report of severe congenital bony deformity, tracheo-esophageal fistula, and anal atresia (vater association) in a baby born to a woman who took dextroamphetamine sulfate with lovastatin during the first trimester of pregnancy. Amphetamines should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. reported in clinical trials and the postmarketing experience of some medications indicated for eatment of ADHD. Although there is no systematic evidence that stimulants cause aggressive i/or or hostility, patients beginning treatment for ADHD should be monitored for the appearance worsening of aggressive behavior or hostility.

calcul timoving to regin alin legis in climateri ages 7 to 10 years with development and intermediate or non-medication treatment groups over 14 months, as well as in naturalistic subgroups of newly methylphenidate-treated and non-medication treated children over 35 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 this effect as well. Therefore, growth should be monitored during treatment with stimulants, and

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

formation for Patients
mohetamines may impair the ability of the patient to engage in potentially hazardous activities such

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 in its appropriate use. A patient Medication Guide is available for Adderall[®]. 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 and to the and to the standard of the standard of the medication Guide and the end of this document.

Veratrum Alkaloids

<u>Urinary Acidifying Agents</u>
(ammonium chloride, sodium acid phosphate, etc.) increase the concentration of the ionized specio of the amphetamine molecule, thereby increasing urinary excretion. Both groups of agents low blood levels and efficacy of amphetamines.

Consult with a declined Proisin double of the three th agents increase blood levels and therefore potentiate the actions of amphet

DOSAGE AND ADMINISTRATION

neurological toxic effects and malignant hyperpyrexia can occur, sometimes with fatal results Amphetamines may counteract the sedative effect of antihist

Meperidine
Amphetamines potentiate the analgesic effect of meperidine

Amphetamines inhibit the hypotensive effect of veratrum alkaloids.

Amphetamines enhance the adrenergic effect of norepinephrine

produce a synergistic anticonvulsant action.

Drug/Laboratory Test Interactions
Amphetamines can cause a significant elevation in plasma corticosteroid levels. This increase is

was administration of the consideration of the cons

greatest in the evening. Amphetamines may interfere with urinary steroid determinations.

Amphetamines may delay intestinal absorption of phenytoin: coadministration of phenytoin m 0 mg: Blue, round, biconvex tablet with one full bisect and two partial bisects debossed with produce a synergistic anticonvulsant action 0 on one side and debossed with dp on the other side. They are available in bottles of 100 tablets

2.5 mg: Peach, round, flat-faced beveled edge tablet debossed with 12.5 on one side and one all bisect and two partial bisects debossed with d | p on the other side. They are available in Prioton Pump Inhibitors
PPIs act on proton pumps by blocking acid production, thereby reducing gastric acidity. When Adderall XR
PPIs act on proton pumps by blocking acid production, thereby reducing gastric acidity. When Adderall XR PPIs act on proton pumps by blocking acid production, thereby reducing gastric acidity, When Adderall XR[®] (20 mg single-dose) was administered concomitantly with the proton pump inhibitor, comparacide (40 mg once daily for 14 days), the median T_{max} of d-amphetamine was decreased by 1.25 hours (from 4 to 2.75 hours), and the median T_{max} of 1-amphetamine was decreased by 2.5 hours (from 5.5 to 3 hours), compared to Adderall XR[®] administered alone. The AUC and C_{max} of each micely were unaffected. Therefore, coadministration of Adderall[®] and proton pump inhibitors should be monitored for changes in clinical effect.

Amphetamine, in the enantiomer ratio present in Adderall[®] (immediate-release)(d- to I- ratio of 3:1), did not adversely affect fertility or early embryonic development in the rat at doses of up to 20 mg/kg/day (approximately 5 times the maximum recommended human dose of 30 mg/day on a mg/m² body surface area basis).

infants born to mothers dependent on amphetamines have an increased risk of premature deliver and low birth weight. Also, these infants may experience symptoms of withdrawal as demonstrate by dysphoria, including agitation, and significant lassitude.

Usage in Nursing Mothers
Amphetamines are excreted in human milk. Mothers taking amphetamines should be advised to refrain from unursing.

commended for use in children under 3 years of age with Attention Deficit Hyperactivity Disorder escribed under INDICATIONS AND USAGE.

have been isolated reports of cardiomyopathy associated with chronic amphetamine use

dyskinesia, dysphoria, depression, tremor, tics, aggression, anger, logorrhea, dermatillomania

yness of the mouth, unpleasant taste, diarrhea, constipation, other gastrointestinal disturbances lorexia and weight loss may occur as undesirable effects.

Iderall[®] (Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate d Amphetamine Sulfate Tablets) is a Schedule II controlled substance.

Amphetamines have been extensively abused. Tolerance, extreme psychological dependence, and severe social disability have occurred. There are reports of patients who have increased the dosage to levels many times higher than recommended. Abrupt cessation following prolonged high dosage

or levels many miles injuried man recommended. Author cossadorn forwing prioringed injurious and diministration results in extreme fatigue and mental depression; changes are also noted on the sleep EEG. Manifestations of chronic intoxication with amphetamines include severe dermatoses, marked no somale, irribality, hyperactivity, and personality changes. The most severe manifestation of chronic ntoxication is psychosis, often clinically indistinguishable from schizophrenia.

angue and depression to stain y follow in the central simulation.

Ardiovascular effects include arrhythmias, hypertension or hypotension and circulatory collapse.
Factorintestinal symptoms include nausea, vomitting, diarrhea, and abdominal cramps. Fatal
Loisoning is usually preceded by convulsions and coma.

as been achieved. Chlorpromazine antagonizes the central stimulant effects of amphetamines and can e used to treat amphetamine intoxication.

Regardless of Indication, amphetamines should be administered at the lowest effective dosage, and dosage should be individually adjusted according to the therapeutic needs and response of the patient. Late evening doses should be avoided because of the resulting insomnia.

Attention Deficit Hyperactivity Disorder Not recommended for children under 3 years of age. In children from 3 to 5 years of age, start wit

2.5 mg daily; daily dosage may be raised in increments of 2.5 mg at weekly intervals until optimal

Narcolepsy seldom occurs in children under 12 years of age; however, when it does, dextroamphetamine sulfate may be used. The suggested initial dose for patients aged 6 to 12 is 5 mg daily; daily dose may be raised in increments of 5 mg at weekly intervals until optimal response is obtained. In patients 12 years of age and older, start with 10 mg daily; daily dosage may be raised in increments of 10 mg at weekly intervals until optimal response is obtained. If bothersome adverse reactions appear (e.g., insomnia or anorexia), dosage should be reduced. Give first dose on awakening; additional doses (1 or 2) at intervals of 4 to 6 hours.

5 mg: White to off-white, round, flat-faced beveled edge tablet with four partial bisects debossed 5 on one side and debossed with dp on the other side. They are available in bottles of 100 table

7.5 mg: Blue, oval, biconvex tablet with two partial bisects debossed with 7.5 on one side and one full bisect and two partial bisects debossed with d \mid p on the other side. They are available

Geriatric Use Adderall[®] has not been studied in the geriatric population.

Fatigue and depression usually follow the central stimulation.

Nonteratogenic Effects

ADVERSE REACTIONS

Central Nervous System

ision blurred, mydriasis.

DRUG ABUSE AND DEPENDENCE

of 100 tablets.
30 mg: Peach, round, flat-faced beveled edge tablet with one full bisect and 2 partial bisects with 3 [0 on one side and dp on the other side. They are available in bottles of 100 tablets.

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. Dispense in a tight, light-resistant container as defined in the USP, with a child-resistant closur

KEEP THIS AND ALL MEDICATIONS OUT OF THE BEACH OF CHILDREN.

All brand names listed are the registered trademarks of their respective owners and are not trademarks of Teva Pharmaceuticals USA.

TEVA PHARMACEUTICALS USA

MEDICATION GUIDE Adderall® (ADD-ur-all)

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

Read the Medication Guide that comes with Adderall® before you or vour 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 $^{ ext{@}}$

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

The following have been reported with use of Adderall® and other stimulant medicines.

. Heart-Related Problems: sudden death in patients who have heart problems or heart

stroke and heart attack in adults increased blood pressure and

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 vou or vour 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 vour 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 $^{f ext{@}}$?

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 Xof a total treatment program for ADHD that may include counseling

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

or other therapies.

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

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
- 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 Adderall[®] is a central nervous be adjusted while taking Adderall[®]. Your doctor will decide whether

medicines

Adderall® can be taken with other

MEDICATION GUIDE Adderall® (ADD-ur-all) (Dextroamphetamine Saccharate, or other therapies. Amphetamine Aspartate,

Amphetamine Sulfate Tablets) narcolensy Read the Medication Guide that

comes with Adderall® before you abused or lead to dependence. Keep or vour child starts taking it and Adderall[®] in a safe place to prevent each time you get a refill. There may misuse and abuse. Selling or giving be new information. This Medication away Adderall® may harm others, Guide does not take the place of and is against the law. talking to your doctor about you or Tell your doctor if you or your child | your child's treatment with Adderall®. have (or have a family history of)

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Dextroamphetamine Sulfate and

K only

defects

- sudden death in patients who have heart problems or heart stroke and heart attack in adults
- increased blood pressure and have an eye problem called glaucoma Tell your doctor if you or your child

defects, high blood pressure, or a are taking or have taken within the family history of these problems. past 14 days an anti-depression Your doctor should check you medicine called a monoamine or your child carefully for heart problems before starting Adderall® Your doctor should check your or your child's blood pressure medicines

treatment with Adderall®. Call your doctor right away if vou or vour 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

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- the arteries sudden death in patients who have moderate to severe high have heart problems or heart blood pressure
- have hyperthyroidism
- are very anxious, tense, or agitated have a history of drug abuse

oxidase inhibitor or MAOI. are sensitive to, allergic to, or had a reaction to other stimulant

and heart rate regularly during 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
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- or depression • tics or Tourette's syndrome
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- thyroid problems

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

R onlv

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thought problems

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Children and Teenagers

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What is Adderall®?

patients with ADHD.

All Patients

Who should not take Adderall®? with use of Adderall $^{f @}$ and otherf |Adderall® should not be taken if you stimulant medicines. or vour child: have heart disease or hardening of . Heart-Related Problems:

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away Adderall® may harm others.

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

and is against the law.

or other therapies.

narcolepsy.

- have any heart problems, heart have a history of drug abuse defects, high blood pressure, or a are taking or have taken within the past 14 days an anti-depression medicine called a monoamine
 - oxidase inhibitor or MAOL • are sensitive to, allergic to, or had a reaction to other stimulant

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- of heart problems such as chest Adderall $^{f @}$ tell vour or vour child's pain, shortness of breath, or doctor about all health conditions fainting while taking Adderall®. (or a family history of) including:
- Mental (Psychiatric) Problems: heart problems, heart defects, high blood pressure new or worse behavior and mental problems including
 - psychosis, mania, bipolar illness, or depression
- new or worse aggressive tics or Tourette's syndrome
 - liver or kidney problems thyroid problems
- new psychotic symptoms (such as seizures or have had an abnormal hearing voices, believing things brain wave test (EEG) that are not true, are suspicious) Tell your doctor if you or your child

are pregnant, planning to become Tell your doctor about any mental pregnant, or breastfeeding. problems you or your child have,

or about a family history of suicide. medicines? bipolar illness, or depression. Tell your doctor about all of the Call your doctor right away if you medicines that you or your child or your child have any new or worsening mental symptoms or

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799-33-100463



Can Adderall® be taken with other

take including prescription and

system stimulant prescription Your doctor will decide whether Adderall® can be taken with other

Reference ID: 3378725

your child take:

 anti-depression 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 vour child take. Keep a list of vour medicines with you to show your doctor and pharmacist.

Do not start any new medicine they have the same condition. It while taking Adderall® without talking to your doctor first.

How should Adderall® be taken? • Take Adderall® exactly as information about Adderall®. If you prescribed. Your doctor may would like more information, talk adjust the dose until it is right for with your doctor. You can ask your you or your child.

 Adderall[®] tablets are usually taken two to three times a day. The first healthcare professionals. For more dose is usually taken when you information about Adderall®, please first wake in the morning. One or two more doses may be taken during the day, 4 to 6 hours apart. What are the ingredients in Adderall®? 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.

Inactive Ingredients: colloidal silicon dioxide, compressible sugar, corn starch. Your doctor may do regular checks magnesium stearate, microcrystalline of the blood, heart, and blood cellulose and saccharin sodium. The pressure while taking Adderall®. 5 mg is a white to off-white tablet, which Children should have their height and contains no color additives. The 7.5 mg weight checked often while taking and 10 mg also contain FD&C Blue #1 Adderall®. Adderall® treatment may Aluminum Lake as a color additive. The be stopped if a problem is found 12.5 mg, 15 mg, 20 mg and 30 mg also during these check-ups. contain FD&C Yellow #6 Aluminum Lake

 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.

about side effects. You may report side medicines 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®

may harm them and it is against

summarizes the most important

doctor or pharmacist for information

contact Teva Pharmaceuticals at

Active Ingredient: dextroamphetamine

dextroamphetamine sulfate and

This Medication Guide has been

TEVA PHARMACEUTICALS USA

Sellersville, PA 18960

Rev. C 6/2013

approved by the U.S. Food and Drug

saccharate, amphetamine aspartate,

1-888-838-2872

amphetamine sulfate

as a color additive

about Adderall® that was written for |

the law. This Medication Guide

Medicines are sometimes prescribed stomach acid medicines for purposes other than those listed Know the medicines that you or in a Medication Guide. Do not use your child take. Keep a list of your Adderall® for a condition for which medicines with you to show your it was not prescribed. Do not give doctor and pharmacist Adderall® to other people, even if

Do not start any new medicine they have the same condition. while taking Adderall® without talking to your doctor first.

cold or allergy medicines that

blood pressure medicines

blood thinner medicines

contain decongestants

seizure medicines

How should Adderall® be taken? • Take Adderall® exactly as information about Adderall®. If you 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

Common side effects include:

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.

effects to FDA at 1-800-FDA-1088. anti-depression medicines including MAOIs

• Store Adderall® in a safe place at room

temperature, 20° to 25°C (68° to 77°F). Keep Adderall® and all medicines

General information about Adderall®

out of the reach of children.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use it was not prescribed. Do not give Adderall® to other people, even if may harm them and it is against the law. This Medication Guide summarizes the most important prescribed. Your doctor may would like more information, talk adjust the dose until it is right for with your doctor. You can ask your doctor or pharmacist for information

> saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate.

> **Inactive Ingredients:** colloidal silicon dioxide, compressible sugar, corn starch, 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 contain FD&C Yellow #6 Aluminum Lake as a color additive

TEVA PHARMACEUTICALS USA Sellersville, PA 18960

Other serious side effects include: slowing of growth (height and

seizures, mainly in patients with a

history of seizures

eyesight changes or blurred vision

headache

stomach ache

vour child take:

 anti-depression medicines effects to FDA at 1-800-FDA-1088. including MAOIs

blood pressure medicines

temperature, 20° to 25°C (68° to 77°F). seizure medicines blood thinner medicines

 cold or allergy medicines that General information about Adderall® contain decongestants

Know the medicines that you or vour child take. Keep a list of vour 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? 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. What are the ingredients in Adderall®? 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 mav

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.

MEDICATION GUIDE Adderall® (ADD-ur-all)

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

m R only

• are very anxious, tense, or agitated Read the Medication Guide that comes with have a history of drug abuse Adderall® before you or your child starts taking it and each time you get a refill. There may be new • are taking or have taken within the past 14 days 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 $^{f @}$? The following have been reported with use of Adderall® and other stimulant medicines.

sudden death in patients who have heart problems or heart defects stroke and heart attack in adults

increased blood pressure and heart rate

<u> 1. Heart-Related Problems:</u>

Tell vour doctor if vou or vour 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 $^{ extbf{@}}$?

How should Adderall $^{f R}$ be taken? Adderall® is a central nervous system stimulant • Take Adderall® exactly as prescribed. Your 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 natients 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 hyperthyroidism

oxidase inhibitor or MAOI.

other stimulant medicines

family history of) including:

tics or Tourette's syndrome

• liver or kidney problems

taken with other medicines

blood pressure medicines

blood thinner medicines

stomach acid medicines

your doctor and pharmacist.

you or your child.

anart

symptoms.

during these check-ups

seizure medicines

decongestants

thyroid problems

test (EEG)

bipolar illness, or depression

less than 3 years old.

have heart disease or hardening of the arteries

an anti-depression medicine called a monoamine

• seizures or have had an abnormal brain wave

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

Your doctor will decide whether Adderall® can be

Especially tell your doctor if you or your child take:

Know the medicines that you or your child take.

Adderall® without talking to your doctor first.

doses may be taken during the day, 4 to 6 hours

• From time to time, your doctor may stop

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®

 If you or your child take too much Adderall® or overdoses, call your doctor or poison control

center right away, or get emergency treatment

treatment may be stopped if a problem is found

Adderall® treatment for a while to check ADHD

Adderall[®] can be taken with or without food.

you first wake in the morning. One or two more U.S. Food and Drug Administration.

anti-depression medicines including MAOIs

will need to be adjusted while taking Adderall®.

have moderate to severe high blood pressure

should know about Adderall®?" for information on reported heart and mental problems.

have an eye problem called glaucoma

Other serious side effects include: slowing of growth (height and weight) in children

What are possible side effects of Adderall®?

See "What is the most important information

seizures, mainly in patients with a history of

eyesight changes or blurred vision

Common side effects include:

stomach ache

• are sensitive to, allergic to, or had a reaction to trouble sleeping

Adderall® is not recommended for use in children • decreased appetite

nervousness

Adderall® may not be right for you or your child. • dizziness Before starting Adderall® tell your or your Adderall® may affect your or your child's ability to child's doctor about all health conditions (or a drive or do other dangerous activities.

Talk to your doctor if you or your child have side heart problems, heart defects, high blood pressure effects that are bothersome or do not go away. • mental problems including psychosis, mania,

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 Tell your doctor if you or your child are pregnant, 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 interact with each other and cause serious side not use Adderall® for a condition for which it was effects. Sometimes the doses of other medicines 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.

 cold or allergy medicines that contain What are the ingredients in Adderall®?

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

Keep a list of your medicines with you to show **Inactive Ingredients:** colloidal silicon dioxide. compressible sugar, corn starch, magnesium Do not start any new medicine while taking 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 doctor may adjust the dose until it is right for Lake as a color additive. The 12.5 mg, 15 mg, 20 mg and 30 mg also contain FD&C Yellow #6 • Adderall® tablets are usually taken two to three Aluminum Lake as a color additive. times a day. The first dose is usually taken when This Medication Guide has been approved by the

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> > Rev. C 6/2013

Reference ID: 3378725

Especially tell your doctor if you or Call your doctor for medical advice X Especially tell your doctor if you or Call your doctor for medical advice X vour child take:

about side effects. You may report side

How should I store Adderall®?

 stomach acid medicines Adderall® for a condition for which

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

magnesium stearate, microcrystalline cellulose and saccharin sodium. The 12.5 mg, 15 mg, 20 mg and 30 mg also

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

Rev. C 6/2013

reported heart and mental problems

weight) in children

about side effects. You may report side

How should I store Adderall®? Store Adderall[®] in a safe place at room

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

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 • Take Adderall® exactly as 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

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

contact Teva Pharmaceuticals at

1-888-838-2872.

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 be stopped if a problem is found 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

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)

 $m R\!\!\!\!/$ 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®.

fainting while taking Adderall®. <u>2. Mental (Psychiatric) Problems:</u> 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 $^{f @}$?

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?

Adderall® Take as exactly 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. without food.

 Adderall[®] can be taken with or From time to time, your doctor may stop Adderall $^{\circledR}$ 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. Reference ID: 3378725

about side effects. You may report side effects to FDA at 1-800-FDA-1088. How should I store Adderall $^{f @}$?

Store Adderall $^{\circledR}$ in a safe place at room temperature, 20° to 25°C (68° to 77°F).

Call your doctor for medical advice

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

information about Adderall®, please contact Teva Pharmaceuticals at 1-888-838-2872. What are the ingredients in Adderall®? Active Ingredient: dextroamphetamine saccharate, amphetamine aspartate,

sulfate

dextroamphetamine

amphetamine sulfate.

as a color additive.

about Adderall® that was written for

healthcare professionals. For more

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

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Rev. C 6/2013

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 OBTAINING MINES 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.

 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
 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 3.13 mg | 4.7 mg | 6.3 mg | 7.8 mg | 9.4 mg | 12.6 mg | 18.8 mg

- b 1.875 mg of Amphetamine Aspartate Monohydrate equivalent to 1.755 mg Amphetamine Aspartate

- 5 mg of Amphetamine Aspartate Monohydrate equivalent to 4.6 mg Amphetamine Aspartate beginning tr

In addition, each tablet contains the following inactive ingredients: colloidal silicon dioxide, compressible sugar, corn starch, magnesium stearate, microcrystalline cellulose and saccharin sodium.

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 hought to block the reuptake of norepinephrine and dopamine into the presynaptic neuron and increase the elease of these monoamines into the extraneuronal space.

Paramachine*

Pharmacokinetics
Dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets contain d-amphetamine and l-amphetamine salts in the ratio of 3:1. Following administration of a single dose 10 or 30 mg of dextroamphetamine saccharate, amphetamine sapartate, dextroamphetamine sulfate and amphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate ablets 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 (1_{1/2}) for d-amphetamine was shorter than the 1_{1/2} of the I-isomer 1,977 to 11 hours vs. 115. to 13.8 hours). The PK parameters (C_{max}, AUC_{p-int}) of 1-and 1-amphetamine increased approximately three-fold from 10 mg to 30 mg indicating dose-proportional pharmacokinetics.

Metabolism and Excretion
Amphetamine is reported to be oxidized at the 4 position of the benzene ring to form 4-hydroxy-amphetamine, 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-amphetamine are both active and each is subsequently oxidized to form 4-hydroxy-amphetamine are both active and each is subsequently oxidized to form 4-hydroxy-amphetamine are both active and each is subsequently oxidized to form 4-hydroxy-amphetamine are both active and each is subsequently oxidized to form 4-hydroxy-amphetamine and the glucuronide and the glycine conjugate hippuric acid. Although the enzymes involved in amphetamine metabolism are a possibility.

Amphetamine is known to inhibit monoamine oxidase, whereas the ability of amphetamine and its metabolisms to inhibit transpreading to inhibit transpreading in the patient with a propositive to inhibit transpreading in the patient with amphetamine and minor inhibition of CYP1A2, 206, and 3A4 by one or more metabolism. An experiment with human microsomes indicate minor inhibition of CYP2D6 by amphetamine and in the propositive of the desired proposit

polymorphisms is more likely to be clinically significant when renal elimination is decreased (see PRECAUTIONS). INDICATIONS AND USAGE Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate and Amphetamine Sulfate Tablets are indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) and Narcolepsy. Attention Deficit Hyperactivity Disorder (ADHD) A diagnosis of Attention Deficit Hyperactivity Di

Special 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.

child and not solely on the presence or the required number of borning and solely on the presence or the required number of borning and an Amphetamine Sulfate Tablets are 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 placement is essential and psychosocial intervention is often helpful. When remedial measures alone are insufficient, the decision to prescribe stimulant medication will depend unanothe devictions to prescribe stimulant medication will depend unanothe devictions to prescribe stimulant medication will depend unanothe devictions to prescribe stimulant medication will depend unanothe devictions.

e-evaluate the long-term usefulness of the drug for the individual patient

Patients with a history of drug abuse.

Although some structural heart problems alone may carry an increased risk of sudden death, stimulant oroducts generally should not be used in children or adolescents with known structural cardiac abnormalities, ardiomyopathy, serious heart rivthm abnormalities, or other serious cardiac problems that may place them it increased vulnerability to the sympathomimetic effects of a stimulant drug (see CONTRAINDICATIONS).

Adults Studden 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 preater likelihood than children of having serious structural cardiac ahonrmalities, cardiomyopathy, serious heart rhythm abnormalities, coronary aftery disease, or other serious cardiac problems. Adults with such abnormalities should also generally not be treated with stimulant drugs (see CONTRAINDICATIONS).

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

Treatment emergent psychotic or Manic Symptoms.

Treatment emergent psychotic or Manic Symptoms, e.g., ha lucinations, delusional thinking, or mania in children and adolescents without prior history of psychotic illness or mania can be caused by stimulants at usual doses. If such symptoms occur, consideration should be given to a possible causal role 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 1.0% (4 patients with events out of 3482 exposed to methylphenidate or amphetamine for several weeks at usual doses) of stimulant-treated patients compared to 0 in placebo-treated patients.

f S mg of Amphetamine Aspartate Monohydrate equivalent to 4.6 mg Amphetamine Aspartate (Anhydrous) as supplied

9 7.5 mg of Amphetamine Aspartate Monohydrate equivalent to 7.03 mg Amphetamine Aspartate (Anhydrous) as supplied

10 addition, each supplied supplied in addition, each supplied in addition treated children over 36 months (to the ages of 10 to 3 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 weight out evidence of growth in weight of or average, a total of about 2 cm less growth in weight out evidence of growth rebuild uning this period of development. Published data are inadequate to determine whether chronic use of amphetamines may cause a similar suppression of growth, howed the fo

There is some clinical evidence that stimulants may lower the convulsive threshold in patients with prior

Their is some came, in patients with prior EEG abnormalities in absence of seizures, and very random history of seizures and no prior EEG evidence of seizures. In the presence of seizures, the drug should be discontinued. Visual Disturbance

Difficulties with accommodation and blurring of vision have been reported with stimulant treatment

General
The least amount of amphetamine feasible should be prescribed or dispensed at one time in order to minimize the possibility of overdosage. Dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets should be used with caution in patients who use other sympathomimetic drugs.

Prescribers or other health professionals should inform patients, their families, and their caregivers about the amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets.

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.

blood levels and therefore potentiate the actions of amphetamines.

Antidepressants, Tricyclic

Amphetamines may enhance the activity of tricyclic or sympathomimetic agents; d-amphetamine with
designamine or protriptyline and possibly other tricyclics cause striking and sustained increases in the
concentration of d-amphetamine in the brain; cardiovascular effects can be potentiated.

Amphetamines may delay intestinal absorption of ethosuximide.

Meperidine
Amphetamines potentiate the analgesic effect of mepe

Methenamine Therapy Jrinary excretion of amphetamines is increased, and efficacy is reduced, by acidifying agents used in

Norepinephrine Amphetamines enhance the adrenergic effect of norepinephrine.

Proton Pump Inhibitors
PPIs act on proton pumps by blocking acid production, thereby reducing gastric acidity. When Adderall
12.5 mg:
Peach, oval, biconvex tablet debossed with 6 over 776 separated by a full score on one side and four

 RP^{\otimes} (20 mg single-dose) was administered concomitantly with the proton pump inhibitor, omeprazole 40 mg once daily for 14 days), the median $T_{\rm max}$ of 4-amphetamine was decreased by 1.25 hours (from to 2.75 hours), and the median $T_{\rm max}$ of 1-amphetamine was decreased by 2.5 hours (from 5.5 to 3 hours), compared to Adderall XR^{\otimes} administered alone. The AUC and $G_{\rm max}$ of each molety were unaffected. Therefore, oadministation of dextroamphetamine sachartate, amphetamine aspartate, dextroamphetamine suifate and amphetamine sulfate tablets and proton pump inhibitors should be monitored for changes in clinical effect

Drug/Laboratory Test Interactions
Amphetamines can cause a significant elevation in plasma corticosteroid levels. This increase is greatest in he evening. Amphetamines may interfere with urinary steroid determinations.

Carcinogenesis/Mutagenesis and Impairment of Fertility

No evidence of carcinogenesis/Mutagenesis and Impairment of Fertility

No evidence of carcinogenicity was found in studies in which d,I-amphetamine (enantiomer ratio of 1:1) was administered to mice and rats in the diet for 2 years at doses of up to 30 mg/kg/day in male mice, 19 mg/kg/day in male mice, 19 mg/kg/day in male and Fermale rats. These doses are approximately 2.4, 15, and 0.8 times, respectively, the maximum recommended human dose of 30 mg/day (child) on a mg/m² body surface area basis.

TEVA PHARMACEUTICALS USA

Amphetamine, in the enantiomer ratio present in dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sultate and amphetamine sultate tablets (immediate-release) (d- to I-ratio of 3·1), was not clastogenic in the mouse bone marrow micronucleus test *in vivo* and was negative when tested in the E. coil component of the Ames test *in vitro*. D, I-Amphetamine (1:1 enantiomer ratio) has been reported to produce a positive response in the mouse bone marrow micronucleus test, an equivocal response in the Ames test, and negative responses in the *in vitro* sister chromatid exchange and chromosomal aberration assays.

Amphetamine, in the enantiomer ratio present in dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets (immediate-release) (d- to I- ratio of 3:1), did not

Pregonancy Category C
Amphetamine, in the enantiomer ratio present in dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets (d- to I- ratio of 3:1), had no apparent effects on embryofetal morphological development or survival when orally administered to pregnant rats and rabbits throughout the period of organogenesis at doses of up to 6 and 16 mg/kg/day, respectively. These doses are approximately 1.5 and 8 times, respectively, the maximum recommended human dose of 30 mg/day (childing on a mg/m² body surface area basis. Fetal malformations and death have been reported in mice following a parenteral administration of d-amphetamine doses of 50 mg/kg/day (approximately 6 times that of a human dose of 30 mg/day (childing) on a mg/m² basis) or greater to pregnant animals. Administration of these doses was also associated with severe maternal toxicity.

Usage in Nursing Mothers

lines are excreted in human milk. Mothers taking amphetamines should be advised to refrain from nursing.

under INDICATIONS AND USAGE. Geriatric Use
Dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine
sulfate tablets have not been studied in the geriatric population.

ADVERSE REACTIONS

Central Nervous System
Psychotic episodes at recommended doses, overstimulation, restlessness, irritability, euphoria, dyskinesia. ysphoria, depression, tremor, tics, aggression, anger, logorrhea, dermatillomania

and weight loss may occur as undesirable effects

Endocrine

Amphetamines have been extensively abused. Tolerance, extreme nsychological dependence, and severe social

implicationness have been extensively autosed. Interfailes, extening psychonolytical dependence, and severe social stability have occurred. There are reports of patients who have increased the dosage to levise many times lighter than recommended. Abrupt cessation following the prolonged high dosage administration results in externe returned tables and the processing the processi OVERDOSAGE

ividual patient response to amphetamines varies widely. Toxic symptoms may occur idiosyncratically

Symptoms
Manifestations of acute overdosage with amphetamines include restlessness, tremor, hyperreflexia, rapid
Manifestations of acute overdosage with amphetamines include restlessness, tremor, hyperreflexia, rapid respiration, confusion, assaultiveness, hallucinations, panic states, hyperpyrexia and rhabdomyolysis Fatigue and depression usually follow the central stimulation. Cardiovascular effects include arrhythmias, hypertension or hypotension and circulatory collapse

Gastrointestinal symptoms include nausea, vomiting, diarrhea, and abdominal cramps. Fatal poisoning is

TreatmentConsult with a Certified Poison Control Center for up to date guidance and advice. Management of acute amphetamine intoxication is largely symptomatic and includes gastric lavage, administration of activated charcoal, administration of a cathartic and sedation. Experience with hemodialysis or peritoneal dialysis is inadequate to permit recommendation in this regard. Acdification of the urine increases amphetamine excretion, but is believed to increase risk of acute renal failure if myoglobinuria is present. If acute, severe hypertension complicates amphetamine overdosage, administration of intravenous phentolamine has been suggested. However, a gradual drop in blood pressure will usually result when sufficient sedation has been achieved. Chlorpromazine antagonizes the central stimulant effects of amphetamines and can be used to treat amphetamine introvication.

Begardless of indication, amphetamines should be administered at the lowest effective dosage, and dosage hould be individually adjusted according to the therapeutic needs and response of the patient. Late evening oses should be avoided because of the resulting insomnia.

Attention Deficit Hyperactivity Disorder Not recommended for children under 3 years of age. In children from 3 to 5 years of age, start with

In children 6 years of age and older, start with 5 mg once or twice daily; daily dosage may be raised in increments of 5 mg at weekly intervals until optimal response is obtained. Only in rare cases will it be necessary to exceed a total of 40 mg per day. Give first dose on awakening; additional doses (1 or 2) at intervals of 4 to 6 hours. Intervals of 4 to 6 nours.

Where possible, drug administration should be interrupted occasionally to determine if there is a recurrence

lepsy dose 5 mg to 60 mg per day in divided doses, depending on the individual patient response

Narcolepsy seldom occurs in children under 12 years of age; however, when it does, dextroamphetamine sulfate may be used. The suggested initial dose for patients aged 6 to 12 is 5 mg daily; daily dose may be raised in increments of 5 mg at weekly intervals until optimal response is obtained. In patients 12 years of age and older, start with 10 mg daily; daily dosage may be raised in increments of 10 mg at weekly intervals until optimal response is obtained. If bothersome adverse reactions appear (e.g., insomina) or anorexia), dosage should be reduced. Give first dose on awakening; additional doses (1 or 2) at intervals of 4 to 6 hours. HOW SUPPLIED

HOW SUPPLIED Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate and Amphetamine Sulfate Tablets are supplied as follows:

5 mg: Blue, oval, biconvex tablet with two partial bisects on one side debossed with 0 over 971 and four partial bisects on the other side debossed with 5. They are available in bottles of 100 tablets.

7.5 mg: Blue, round, flat-faced, beveled-edge tablet debossed with 0 over 775 on ne side and two partial bisects and a full score on the other side debossed with 7 | 1/2. They are available in bottles of 100 tablets. and a full scarce of users size devoices until 1 [1] in liney all evaluation in locates of not abuses. Blue, out 3, full-faced, better dependently and two partial bisects on one side debossed with b over 972 and two partial bisects and a full score on the other side debossed with 1 [0. They are available in bottles of 100 tablets.

partial bisects on the other side debossed with 12 1/2. They are available in bottles of 100 tablets. Peach, round, flat-faced, beveled-edge tablet debossed with 0 view 777 on one side and two partial bisects and a full score on the other side debossed with 1 | 15. They are available in bottles.

of 100 tablets.

20 mg: Peach, oval, flat-faced, beveled-edge tablet with two partial bisects on one side debossed with be over 973 and two partial bisects and a full score on the other side debossed with 2 | 0. They are available in bottles of 100 tablets.

30 mg: Peach, oval, biconvex tablet with two partial bisects on one side debossed with be over 974 and two partial bisects and a full score on the other side debossed with 3 | 0. They are available in bottles of 100 tablets.

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].

MEDICATION GUIDE

DEXTROAMPHETAMINE SACCHARATE, 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**

- R∕oniv

A number of studies in rodents indicate that prenatal or early postnatal exposure to amphetamine (d- or d,I-), at doses similar to those used clinically, can result in long-term neurochemical and behavioral affects include learning and memory deficits, altered locomotor activity, and changes in sexual function.

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, Pediatric Use
Long-term effects of amphetamines in children have not been well established. Amphetamines are not recommended for use in children under 3 years of age with Attention Deficit Hyperactivity Disorder described and amphetamine sulfate tablets. 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,

1. Heart-Related Problems:

tablets and other stimulant medicines.

• sudden death in patients who have heart problems | Who should not take dextroamphetamine saccharate, or heart defects

dextroamphetamine sulfate and amphetamine sulfate

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.

for heart problems before starting dextroamphetamine | • have moderate to severe high blood pressure saccharate, amphetamine aspartate, dextroamphetamine | • have hyperthyroidism sulfate and amphetamine sulfate tablets. Your doctor should check your or your child's • are very anxious, tense, or agitated

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 aspartate, dextroamphetamine sulfate

2. Mental (Psychiatric) Problems

amphetamine sulfate tablets.

All Patients

- new or worse behavior and thought problems
- new or worse bipolar illness new or worse aggressive behavior or hostility
- Children and Teenagers believing things that are not true, are suspicious)

or new manic symptoms child have, or about a family history of suicide, bipolar illness, or depression.

| Call your doctor right away if you or your child have | • liver or kidney problems | any new or worsening mental symptoms or problems | • thyroid problems amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets, especially seeing or hearing things that are not real, believing things planning to become pregnant, or breastfeeding. that are not real, or are suspicious. What are dextroamphetamine saccharate,

amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets? Dextroamphetamine saccharate, amphetamine you or your child take including prescription and

system stimulant prescription medicine. It is used Xfor 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.

and amphetamine sulfate tablets? Dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets should not be taken if

amphetamine aspartate, dextroamphetamine sulfate

- you or your child: Your doctor should check you or your child carefully | • have heart disease or hardening of the arteries

 - have an eye problem called glaucoma
- |blood pressure and heart rate regularly during | have a history of drug abuse treatment with dextroamphetamine saccharate, • 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 new psychotic symptoms (such as hearing voices, | child's doctor about all health conditions (or a family history of) including:

- heart problems, heart defects, high blood pressure Tell your doctor about any mental problems you or your | • mental problems including psychosis, mania, bipolar
 - illness, or depression • tics or Tourette's syndrome
- while taking dextroamphetamine saccharate, seizures or have had an abnormal brain wave test

Can dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets be taken with other medicines?

Tell your doctor if you or your child are pregnant,

Tell your doctor about all of the medicines that aspartate, dextroamphetamine sulfate and nonprescription medicines, vitamins, and herbal Rev. C 6/2013 amphetamine sulfate tablets are a central nervous supplements. Dextroamphetamine saccharate,

MEDICATION GUIDE DEXTROAMPHETAMINE SACCHARATE.

DEXTROAMPHETAMINE SULFATE AND AMPHETAMINE ASPARTATE 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**

${ m R}$ 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 | Who should not take dextroamphetamine saccharate 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

history of these problems. Your doctor should check you or your child carefully for heart problems before starting dextroamphetamine | • have moderate to severe high blood pressure

sulfate and amphetamine sulfate tablets. Your doctor should check your or your child's • are very anxious, tense, or agitated |blood pressure and heart rate regularly during | • have a history of drug abuse 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.)

or new manic symptoms 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 • thyroid problems while taking dextroamphetamine saccharate. amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets, especially seeing that are not real, or are suspicious.

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

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.

and amphetamine sulfate tablets? Dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and problems, heart defects, high blood pressure, or a family amphetamine sulfate tablets should not be taken if

amphetamine aspartate, dextroamphetamine sulfate

- you or your child: have heart disease or hardening of the arteries
- saccharate, amphetamine aspartate, dextroamphetamine | have hyperthyroidism
 - have an eye problem called glaucoma
- treatment with dextroamphetamine saccharate, 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 believing things that are not true, are suspicious) family history of) including:

- heart problems, heart defects, high blood pressure |Tell your doctor about any mental problems you or your| • mental problems including psychosis, mania, bipolar illness, or depression
 - tics or Tourette's syndrome
 - liver or kidney problems
 - seizures or have had an abnormal brain wave test

Tell your doctor if you or your child are pregnant, or hearing things that are not real, believing things planning to become pregnant, or breastfeeding. Can dextroamphetamine saccharate, amphetamine

sulfate tablets be taken with other medicines? Tell your doctor about all of the medicines that Dextroamphetamine saccharate, amphetamine you or your child take including prescription and

aspartate, dextroamphetamine sulfate and amphetamine

aspartate, dextroamphetamine sulfate and nonprescription medicines, vitamins, and herbal amphetamine sulfate tablets are a central nervous supplements. Dextroamphetamine saccharate,

Reference ID: 3378725

799-33-100462

BEXTROMAPHETAMINE
SACCHMARTE:
AMPHETAMINE ASPARTA
BEXTROMAPHETAMINE
SULFATE AND AMPHETA
SULFATE TABLETS
- 0871 0777
- 0775 0973
- 0775 0973
- 0776 9778
- 0776 9778
- 0776 9778
- 0776 9778
- 0776 9778
- 0776

amphetamine aspartate, dextroamphetamine sulfate and • eyesight changes or blurred vision amphetamine sulfate tablets and some medicines may **Common side effects include:** interact with each other and cause serious side effects. • headache Sometimes the doses of other medicines will need to be • stomach ache adjusted while taking dextroamphetamine saccharate. • trouble sleeping amphetamine aspartate, dextroamphetamine sulfate • decreased appetite and amphetamine sulfate tablets.

Your doctor will decide whether dextroamphetamine dizziness saccharate, amphetamine aspartate, Dextroamphetamine saccharate, amphetamine I dextroamphetamine sulfate and amphetamine sulfate aspartate, dextroamphetamine sulfate and 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
- stomach acid medicines

Know the medicines that you or your child take. Keep and amphetamine sulfate tablets? a list of your medicines with you to show your doctor • Store dextroamphetamine saccharate, amphetamine and pharmacist.

Do not start any new medicine while taking dextroamphetamine saccharate, amphetamine amphetamine sulfate tablets without talking to your doctor first.

How should dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine General information about dextroamphetamine

- Take dextroamphetamine saccharate, sulfate and amphetamine sulfate tablets. amphetamine aspartate, dextroamphetamine until it is right for you or your child.
- hours apart.
- without food.
- dextroamphetamine saccharate, amphetamine dextroamphetamine sulfate and amphetamine sulfate check ADHD symptoms.
- blood, heart, and blood pressure while taking Teva Pharmaceuticals at 1-888-838-2872. aspartate, dextroamphetamine sulfate and You may report side effects to FDA at 1-800-FDA-1088. dextroamphetamine saccharate, amphetamine sulfate tablets? aspartate, dextroamphetamine sulfate and Active Ingredients: dextroamphetamine saccharate, amphetamine aspartate, and amphetamine sulfate. saccharate, dextroamphetamine sulfate and amphetamine sulfate

 Inactive Ingredients: colloidal silicon dioxide, found during these check-ups.
- If you or your child take too much dextroamphetamine saccharate, amphetamine amphetamine sulfate tablets or overdoses, call vour doctor or poison control center right away, or get emergency treatment.

saccharate, amphetamine aspartate, dextroamphetamine Food and Drug Administration. 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

• Reizures compinity in the matter with a history of seizures

- nervousness

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 | • seizure medicines your doctor or pharmacist for more information.

• cold or allergy medicines that contain decongestants How should I store dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate

- aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets in a safe place at room | **Do not start any new medicine while taking** temperature, 20° to 25°C (68° to 77°F).
- amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets and all medicines out of the reach of children.

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

Medicines are sometimes prescribed for purposes sulfate and amphetamine sulfate tablets exactly other than those listed in a Medication Guide. Do as prescribed. Your doctor may adjust the dose not use dextroamphetamine saccharate, amphetamine | aspartate, dextroamphetamine sulfate and amphetamine • Dextroamphetamine saccharate, amphetamine sulfate tablets for a condition for which it was not aspartate, dextroamphetamine sulfate and prescribed. Do not give dextroamphetamine saccharate. amphetamine sulfate tablets are usually taken two amphetamine aspartate, dextroamphetamine sulfate and to three times a day. The first dose is usually taken amphetamine sulfate tablets to other people, even if they when you first wake in the morning. One or two have the same condition. It may harm them and it is more doses may be taken during the day, 4 to 6 against the law. This Medication Guide summarizes the most important information about dextroamphetamine • Dextroamphetamine saccharate, amphetamine saccharate, amphetamine aspartate, dextroamphetamine I aspartate, dextroamphetamine sulfate and sulfate and amphetamine sulfate tablets. If you would amphetamine sulfate tablets can be taken with or like more information, talk with your doctor. You can ask your doctor or pharmacist for information about • From time to time, your doctor may stop dextroamphetamine saccharate, amphetamine aspartate, aspartate, dextroamphetamine sulfate and tablets that was written for healthcare professionals. amphetamine sulfate tablets treatment for a while to For additional information on dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine • Your doctor may do regular checks of the sulfate and amphetamine sulfate tablets, please contact I

dextroamphetamine saccharate, amphetamine Call your doctor for medical advice about side effects.

amphetamine sulfate tablets. Children should have What are the ingredients in dextroamphetamine their height and weight checked often while taking saccharate, amphetamine aspartate, dextroamphetamine

amphetamine sulfate tablets. Dextroamphetamine amphetamine aspartate, dextroamphetamine sulfate

tablets treatment may be stopped if a problem is 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 aspartate, dextroamphetamine sulfate and 30 mg also contain FD&C Yellow #6 Aluminum Lake. KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

What are possible side effects of dextroamphetamine This Medication Guide has been approved by the U.S.

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amphetamineaspartate, dextroamphetamine sulfate and • eyesight changes or blurred vision amphetamine sulfate tablets and some medicines may **Common side effects include:** interact with each other and cause serious side effects. • headache Sometimes the doses of other medicines will need to be • stomach ache adjusted while taking dextroamphetamine saccharate, • trouble sleeping amphetamine aspartate, dextroamphetamine sulfate • decreased appetite and amphetamine sulfate tablets.

Your doctor will decide whether dextroamphetamine • dizziness saccharate, amphetamine aspartate, Dextroamphetamine saccharate, amphetamine dextroamphetamine sulfate and amphetamine sulfate aspartate, dextroamphetamine sulfate and 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
- blood thinner medicines
- cold or allergy medicines that contain decongestants How should I store dextroamphetamine saccharate, stomach acid medicines

Know the medicines that you or your child take. Keep and amphetamine sulfate tablets? a list of your medicines with you to show your doctor • Store dextroamphetamine saccharate, amphetamine and pharmacist.

dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and • Keep dextroamphetamine saccharate, | aspartate, dextroamphetamine sulfate and • Keep dextroamphetamine saccharate, amphetamine sulfate tablets without talking to your doctor first.

> How should dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine General information about dextroamphetamine sulfate and amphetamine sulfate tablets be taken? saccharate, amphetamine aspartate, dextroamphetamine

- Take dextroamphetamine saccharate, sulfate and amphetamine sulfate tablets. amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets exactly other than those listed in a Medication Guide. Do as prescribed. Your doctor may adjust the dose not use dextroamphetamine saccharate, amphetamine until it is right for you or your child.
- hours apart.
- aspartate, dextroamphetamine sulfate and sulfate and amphetamine sulfate tablets. If you would amphetamine sulfate tablets can be taken with or like more information, talk with your doctor. You can without food.
- dextroamphetamine saccharate, amphetamine dextroamphetamine sulfate and amphetamine sulfate aspartate, dextroamphetamine sulfate and tablets that was written for healthcare professionals. amphetamine sulfate tablets treatment for a while to For additional information on dextroamphetamine check ADHD symptoms.
- blood, heart, and blood pressure while taking Teva Pharmaceuticals at 1-888-838-2872. aspartate. dextroamphetamine sulfate and You may report side effects to FDA at 1-800-FDA-1088. amphetamine sulfate tablets. Children should have What are the ingredients in dextroamphetamine their height and weight checked often while taking saccharate, amphetamine aspartate, dextroamphetamine dextroamphetamine saccharate, amphetamine sulfate tablets? aspartate, dextroamphetamine sulfate and Active Ingredients: dextroamphetamine saccharate, saccharate, amphetamine aspartate, and amphetamine sulfate. dextroamphetamine sulfate and amphetamine sulfate

 Inactive Ingredients: colloidal silicon dioxide, tablets treatment may be stopped if a problem is found during these check-ups
- If you or your child take too much aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets or overdoses, call vour doctor or poison control center right away, or get emergency treatment.

saccharate, amphetamine aspartate, dextroamphetamine Food and Drug Administration. 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

- nervousness

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.

amphetamine aspartate, dextroamphetamine sulfate

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

Medicines are sometimes prescribed for purposes aspartate, dextroamphetamine sulfate and amphetamine Dextroamphetamine saccharate, amphetamine sulfate tablets for a condition for which it was not aspartate, dextroamphetamine sulfate and prescribed. Do not give dextroamphetamine saccharate, amphetamine sulfate tablets are usually taken two amphetamine aspartate, dextroamphetamine sulfate and to three times a day. The first dose is usually taken amphetamine sulfate tablets to other people, even if they when you first wake in the morning. One or two have the same condition. It may harm them and it is more doses may be taken during the day, 4 to 6 against the law. This Medication Guide summarizes the most important information about dextroamphetamine • Dextroamphetamine saccharate, amphetamine saccharate, amphetamine aspartate, dextroamphetamine ask your doctor or pharmacist for information about • From time to time, your doctor may stop dextroamphetamine saccharate, amphetamine aspartate, saccharate, amphetamine aspartate, dextroamphetamine • Your doctor may do regular checks of the sulfate and amphetamine sulfate tablets, please contact

dextroamphetamine saccharate, amphetamine Call your doctor for medical advice about side effects.

amphetamine sulfate tablets. Dextroamphetamine amphetamine aspartate, dextroamphetamine sulfate

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 dextroamphetamine saccharate, amphetamine 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.

What are possible side effects of dextroamphetamine This Medication Guide has been approved by the U.S.

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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

$m R\!\!\!\!/$ 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 antique to the saccharate and antique to the saccharate to the saccharate and antique to the saccharate and the sacchara

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 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 dextroamphetamine amphetamine sulfate and tablets mav 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 amphetamine saccharate. 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 amphetamine sulfate tablets without talking to your doctor first.

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

- 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 dextroamphetamine sulfate aspartate. 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.
- amphetamine Dextroamphetamine saccharate, aspartate. dextroamphetamine sulfate 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 saccharate, dextroamphetamine amphetamine aspartate, dextroamphetamine sulfate amphetamine sulfate tablets. Children should have their height and weight checked often while taking dextroamphetamine saccharate, amphetamine dextroamphetamine sulfate amphetamine sulfate tablets. Dextroamphetamine amphetamine saccharate. aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets treatment may be stopped if a problem is found during these check-ups.
- your • If or child take you too much dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate 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?

"What is the most important information I See 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
- Reference 和如!ysig 78时erts 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 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 dextroamphetamine sulfate aspartate. amphetamine sulfate tablets in a safe place at room temperature, 20° to 25°C (68° to 77°F).
- dextroamphetamine Keep saccharate. amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets and all medicines out of the reach of children.

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. 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.

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

TEVA PHARMACEUTICALS USA

Sellersville, PA 18960

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/s/	-
KOUNG U LEE 09/25/2013	

For Wm. Peter Rickman