MISUSE OF AMPHETAMINE MAY CAUSE SUDDEN DEATH AND SERIOUS CARDIOVASCULAR

# DESCRIPTION

EACH TABLET CONTAINS	5 mg	7.5 mg	10 mg	12.5 mg	15 mg	20 mg	30 m
Dextroamphetamine Saccharate	1.25 mg	1.875 mg	2.5 mg	3.125 mg	3.75 mg	5 mg	7.5 m
Amphetamine Aspartate Monohydrate Equivalent	1.25 mg <sup>a</sup>	1.875 mg <sup>b</sup>	2.5 mg <sup>c</sup>	3.125 mg <sup>d</sup>	3.75 mg <sup>e</sup>	5 mg <sup>f</sup>	7.5 mg
Dextroamphetamine Sulfate, USP	1.25 mg	1.875 mg	2.5 mg	3.125 mg	3.75 mg	5 mg	7.5 m
Amphetamine Sulfate, USP	1.25 mg	1.875 mg	2.5 mg	3.125 mg	3.75 mg	5 mg	7.5 m
Total Amphetamine Base Equivalence	3.13 mg	4.7 mg	6.3 mg	7.8 mg	9.4 mg	12.6 mg	18.8 n

- ASPARTATE (ARMYOTOUS) as Supplied: 3.75 mg of Amphetamine Aspartate Monohydrate equivalent to 3.51 mg Amphetamine Aspartate
- (Anhydrous) as supplied (Anhydrous) as supplied 5 mg of Amphetamine Aspartate Monohydrate equivalent to 4.6 mg Amphetamine Aspartate (Anhydrous) as supplied 7.5 mg of Amphetamine Aspartate Monohydrate equivalent to 7.03 mg Amphetamine Aspartate

(Aminyurus) as supplied

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.

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

presynaptic neuron and increase the temase of the presence of

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

nvolved with formation of 4-hydroxy-amphetamine. Since CYP2D6 is genetically polymorphic, population ariations in amphetamine metabolism are a possibility.

Amphetamine is known to inhibit monoamine oxidase, whereas the ability of amphetamine and its metabolites to inhibit various P450 isozymes and other enzymes has not been adequately elucidated. In vitro experiments with human microsomes indicate minor inhibition of CYP206 by amphetamine and minor inhibition of CYP1A2, 2D6, and 3A4 by one or more metabolites. However, due to the

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 pka of 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 acticic pHs and high flow rates result in increased renal elimination to clearances greater than glomerular filtration rates, indicating the involvement of active secretion. Urinary

Attention Deficit Hyperactivity Disorder (ADHD)

A diagnosis of Attention Deficit Hyperactivity Disorder (ADHD)

A diagnosis of Attention Deficit Hyperactivity Disorder (ADHD; DSM-IV®) implies the presence of hyperactive-impulsive or inatentive 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, 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: fidgetling/squirming; leaving seat; inappropriate running/climbing; 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.

pecinic etulougy or lins syntoline is dininulum, and directs in lo shiple diagnostic less. Audiquate diagnossi-quiries the use not only of medical but of special psychological, educational, and social resources, earning may or may not be impaired. The diagnosis must be based upon a complete history and valuation of the child and not solely on the presence of the required number of DSM-IV® characteristics.

Need for Comprehensive Treatment Program
Adderall® is indicated as an integral part of a total treatment program for ADHD that may include other Adderaile\* is indicated as an integral part of a total treatment program for AUHU 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 upon the physician's assessment of the chronicity and severity of the child's symptoms.

# 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.

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

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

to the sympathomimetic effects of a stimulant drug (see CONTRAINDICATIONS

Soucer locations, stores, and injudential infaction in later been reported in adults earning similiant longs at a usual doses for ADHD. Although the role of stimulants in these adult cases is also unknown, adults have a greater likelihood than children of having serious structural cardiac abnormalities, cardiomyopathy, serious heart rhythm abnormalities, coronary artery disease, or other serious cardiac problems. Adults with such abnormalities should also generally not be treated with stimulant drugs (see CONTRAINDICATIONS).

# diovascular Status in Patients Being Treated With Stimulant Medications scents, or adults who are being considered for treatment with stimulant medications should history (including assessment for a family history of sudden death or ventricular arrhythmia) am 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 ymptoms such as exertional chest pain, unexplained syncope, or other symptoms suggestive of cardiac se during stimulant treatment should undergo a prompt cardiac evaluation

### Psychiatric Adverse Events

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

amuser and adversements without prior insury or psychotic liness 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-erm, placebo-controlled studies, such symptoms occurred in about 0.1% (4 patients with events out of 5482 exposed to methylphenidate or amphetamine for several weeks at usual doses) of stimulant-reated patients compared to 0 in placebo-treated patients.

Careful follow-up of weight and height in children ages 7 to 10 years who were randomized to either methylphenidate or non-medication treatment groups over 14 months, as well as in naturalistic subgroups of newly methylphenidate-treated and non-medication treated children over 36 months (to the ages of 10 to 13 years), suggests that consistently medicated children (ue., 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 neight of a stream, 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 patients who are not growing or gaining weight as expected may need to have their treatment interrupted

history of seizure, in patients with prior EEG abnormalities in absence of seizures, and very rarely, in patients without a history of seizures and no prior EEG evidence of seizures. In the presence of seizures, the drug should be discontinued. Visual Disturbance

PRECAUTIONS

minimize the possibility of overdosage. Adderall® should be used with caution in patients who use other sympathomimetic drugs.

Information for Patients
Amphetamines may impair the ability of the patient to engage in potentially hazardous activities such as operating machinery or vehicles; the patient should therefore be cautioned accordingly.
Prescribers or other health professionals should inform patients, their families, and their caregivers about

Pressures to outer learnt protessinals shown interin patients, time rathless, and tient categories 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<sup>®</sup>. 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.

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

ines may enhance the activity of tricyclic or sympathomimetic agents: d-amphetamine wi

MAO Inhibitors
MAO antidepressants, as well as a metabo ite of furazolidone, slow amphetamine metabolism. This slowing potentiates amphetamines, increasing their effect on the release of norepinephrine and other monor from adrenergic nerve endings, this causa headaches and other signs of hypertensive crisis. A vaneurological toxic effects and malignant hyperpyrexia can occur, sometimes with fatal results.

Amphetamines may antagonize the hypotensive effects of antihypertensive

Meperidine
Amphetamines potentiate the analgesic effect of meperidine.

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

Norepinephrine
Amphetamines enhance the adrenergic effect of norepinephrine.

Carcinogenesis/Mutagenesis and Impairment of Fertility

Veratrum Alkaloids

Amphetamines may delay intestinal absorption of phenobarbital; coadministration of phenobarbital ma

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

arcinogenesis/Mutagenesis and Impairment of Fertility
to evidence of carcinogenicity was found in studies in which d,I-amphetamine (enantiomer ratio of 1:1)
as administered to mice and rats in the diet for 2 years at doses of up to 30 mg/kg/day in male mice,

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

mines may delay intestinal absorption of phenytoin; coadministration of phenytoin m

2.5 mg: Peach, round, flat-faced beveled edge tablet debossed with 12.5 on one side and one Ill bisect and two partial bisects debossed with d | p on the other side. They are available ir

PPIs act on proton pumps by blocking acid production, thereby reducing gastric acidity. When Adderall XR<sup>®</sup> (20 mg single-dose) was administered concenitantly with the proton pump inhibitor, comparacide (40 mg once daily for 14 days), the median T<sub>max</sub> of d-amphetamine was decreased by 1.25 hours (from 4 to 2.75 hours), and the median T<sub>max</sub> of l-amphetamine was decreased by 2.5 hours (from 5.5 to 3 hours), compared to Adderall XR<sup>®</sup> administered alone. The AUC and C<sub>max</sub> of each miosity were unaffected. Therefore, coadministration of Adderall<sup>®</sup> and proton pump inhibitors should be monitored for changes in clinical effect.

of four dateies.

30 mg: Peach, round, flat-faced beveled edge tablet with one full bisect and 2 partial bisec 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

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

mg: Blue, round, biconvex tablet with one full bisect and two partial bisects debossed with

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN. Il brand names listed are the registered trademarks of their respective owners and an

This label may not be the latest approved by FDA For current labeling information, please visit https://www.fda.gov/drugsatfda

# MEDICATION GUIDE Adderall® (ADD-ur-all)

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

# $\mathbf{R}$ 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

**Heart-Related Problems:** 

sudden death in natients 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 vou or your child have any signs of heart problems such as chest pain, shortness of breath, or | fainting while taking Adderall $^{f @}$  .

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

problems you or your child have, or about a family history of suicide, bipolar illness, or depression.

Call your doctor right away if you or your child have any new or worsening mental symptoms or problems while taking Adderall® especially seeing or hearing things that are not real, believing things that are not real, or are suspicious.

## What is Adderall®? Adderall® is a central nervous

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

Adderall<sup>®</sup> should be used as a part Xof a total treatment program for ADHD that may include counseling

Adderall $^{\circledR}$  is also used in the treatment of a sleep disorder called

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 street druas.

## Who should not take Adderall®? Adderall® should not be taken if you or your child.

- have heart disease or hardening of the arteries sudden death in natients who have moderate to severe high have heart problems or heart
- blood pressure have hyperthyroidism have an eye problem called
- heart rate alaucoma 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

use in children less than 3 years old. Adderall® may not be right for you or your child. Before starting Adderall $^{f f B}$  tell vour or vour child's doctor about all health conditions

- heart problems, heart defects, high blood pressure
- psychosis, mania, bipolar illness, or depression
- tics or Tourette's syndrome

brain wave test (EEG)

seizures or have had an abnormal

Tell your doctor if you or your child are pregnant, planning to become pregnant, or breastfeeding.

medicines? Tell your doctor about all of the

medicines that you or your child take including prescription and 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® can be taken with other medicines.

MEDICATION GUIDE Adderall® (ADD-ur-all)

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

# **K** only

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

with use of Adderall® and other stimulant medicines. **Heart-Related Problems:** 

defects 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 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 be adjusted while taking Adderall®.

system stimulant prescription Your doctor will decide whether medicine. It is used for the treatment of Attention-Deficit Hyperactivity medicines. **Disorder (ADHD).** Adderall® may help increase attention and decrease impulsiveness and hyperactivity in patients with ADHD.

MEDICATION GUIDE Adderall<sup>®</sup> should be used as a part XAdderall® (ADD-ur-all)

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

Who should not take Adderall®? 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

Tell your doctor if you or your child have any heart problems, heart | • have a history of drug abuse 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®. use in children less than 3 years old. Call your doctor right away i vou or vour child have any signs of heart problems such as chest pain, shortness of breath, or fainting while taking Adderall $^{\otimes}$ .

2. Mental (Psychiatric) Problems: All Patients new or worse behavior and

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

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

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.

Adderall® should not be taken if you or your child. have heart disease or hardening of

 have moderate to severe high blood pressure

have an eye problem called

- are taking or have taken within the past 14 days an anti-depression medicine called a monoamine
- are sensitive to, allergic to, or had a reaction to other stimulant

use in children less than 3 years old. Adderall® may not be right for you or your child. Before starting Adderall $^{\otimes}$  tell vour or vour child's doctor about all health conditions

(or a family history of) including:

psychosis, mania, bipolar illness or depression

• tics or Tourette's syndrome

 liver or kidney problems thyroid problems

brain wave test (EEG) Tell your doctor if you or your child are pregnant, planning to become

Can Adderall® be taken with other medicines?

Tell your doctor about all of the medicines that you or your child

Adderall® can be taken with other



799-33-100463

dvanced arteriosclerosis, sym nynerthyroidism, known hyperse

19 mgkydday in female mice, and 5 mg/kg/day in male and female rats. These doses are approximately 2.4, 1.5, and 0.8 times, respectively, the maximum recommended human dose of 30 mg/day [child] on a mg/m² body surface are

Pregnancy Category C
Amphetamine, in the enantiomer ratio present in Adderall® (d- to I- ratio of 3:1), had no apparent effects on pregamine, mile chandwisher has piezen in Auderian— (or to Frainio 27), hear on appearin effects of hypotetal morphological development or survival when oral y administered to pregnant rats and rabbits oughout the period of organogenesis at doses of up to 6 and 16 mg/kg/day, respectively. These doses are roximately 1.5 and 8 times, respectively, the maximum recommended human dose of 30 mg/day [child] a mg/m² body surface area basis. Fetal malformations and death have been reported in mice following enteral administration of d-ampletamine doses of 50 mg/kg/day approximately 6 times that of a human parenteral administration of d-amphetamine doses of 50 mg/kg/day (approximately 6 to dose of 30 mg/day (child) on a mg/m2 basis) or greater to pregnant animals. Administ, was also associated with severe maternal toxicity.

A number of studies in rodente interest in the control of the contro

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

There are no adequate and well-controlled studies in pregnant women. There has been one report of are no eucqueze ariu wein-cuniumed studies in pregnant women. There has been one report of severe congenial 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.

Nonteratogenic Effects

ecommended for use in children under 3 years of age with Attention Deficit Hyperactivity Disorde lescribed under INDICATIONS AND USAGE.

**Geriatric Use** Adderall<sup>®</sup> has not been studied in the geriatric population ADVERSE REACTIONS

Central Nervous System

ryness of the mouth, unpleasant taste, diarrhea, constipation, other gastrointestinal disturbances. norexia and weight loss may occur as undesirable effects. Urticaria, rash, hypersensitivity reactions including angioedema and anaphylaxis. Serious skin rashes

# nnotence, changes in libido.

**Usage in Nursing Mothers** 

Adderall® (Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate and Amphetamine Sulfate Tablets) is a Schedule II controlled substance. to levels many times nigner man recommended. Adrupt cessation following protonged night doday, administration results in extreme fatigue and mental depression; changes are also noted on the sleep EEG. Manifestations of chronic intoxication with amphetamines include severe dermatoses, market

dividual patient response to amphetamines varies widely. Toxic symptoms may occur iosyncratically at low doses. nptoms inflestations of acute overdosage with amphetamines include restlessness, tremor, hyperreflexia, rapid piration, confusion, assaultiveness, hallucinations, panic states, hyperpyrexia and rhabdomyolysis.

atique and depression usually follow the central stimulation.

scular effects include arrhythmias, hypertension or hypotension and circulatory collapse. Gastrointestinal symptoms include nausea, vomiting, diarrhea, and abdominal cramps. Fatal poisoning is usually preceded by convulsions and coma. mphetamine intoxication is largely symptomatic and includes gastric lavage, administration of activated narcoal, administration of a cathartic and sedation. Experience with hemodialysis or peritoneal dialysis inadequate to permit recommendation in this regard. Acidification of the urine increases amphetamine cretion, but is believed to increase risk of acute renal failure if myoglobinuria is present. If acute, severe

Australia, but sendeved in inclased start and audit ration afficient in hygoridania is present in acute, service yearension complicates amphetamine overdosage, administration of intravenous phentolamine has een suggested. However, a gradual drop in blood pressure will usually result when sufficient sedation as been achieved. Chlorpromasine antagonizes the central stimulant effects of amphetamines and can e used to treat amphetamine intoxication. DOSAGE AND ADMINISTRATION JUSABLE AND AUMINISTIATION
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 valtent. Late evening doses should be avoided because of the resulting insomnia.

ttention Deficit Hyperactivity Disorder Autention Deficit Hyperactivity Disorder

Not recommended for children under 3 years of age. In children from 3 to 5 years of age, start with 2.5 mg daily; daily dosage may be raised in increments of 2.5 mg at weekly intervals until optima

sponse is obtained.

children 6 years of age and older, start with 5 mg once or twice daily; daily dosage may be raised increments of 5 mg at weekly intervals until optimal response is obtained. Only in rare cases will be necessary to exceed a total of 40 mg per day. Give first dose on awakening; additional doses (1 r 2) at intervals of 4 to 6 hours. Where possible, drug administration should be interrupted occasionally to determine if there is a

recurrence of behavioral symptoms sufficient to require continued therap ual dose 5 mg to 60 mg per day in divided doses, depending on the individual patient responsi obtained. In patients 12 years of age and older, start with 10 mg daily; daily dosage may be ised in increments of 10 mg at weekly intervals until optimal response is obtained. If bothersome

lverse reactions appear (e.g., insomnia or anorexia), dosage should be reduced. Give first dose or wakening; additional doses (1 or 2) at intervals of 4 to 6 hours. Tell your doctor about any mental 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 | p on the other side. They are available

Adderall® is not recommended for

(or a family history of) including:

mental problems including

 liver or kidney problems thyroid problems

Can Adderall® be taken with other

nonprescription medicines, be adjusted while taking Adderall®. Your doctor will decide whether

ADHD that may include counseling or other therapies.

street drugs.

or vour child.

the arteries

glaucoma

medicines

blood pressure

or depression

thyroid problems

medicines?

blood pressure

have hyperthyroidism

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

Tell your doctor if you or your child

Adderall® should not be taken if you

have heart disease or hardening of

have moderate to severe high

have an eye problem called

are very anxious, tense, or agitated

are taking or have taken within the

are sensitive to, allergic to, or

Adderall® is not recommended for

Adderall® may not be right for

you or your child. Before starting

Adderall® tell your or your child's

doctor about all health conditions

heart problems, heart defects, high

mental problems including

seizures or have had an abnormal

Tell your doctor if you or your child

are pregnant, planning to become

Can Adderall® be taken with other

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® can be taken with other

• tics or Tourette's syndrome

liver or kidney problems

brain wave test (EEG)

pregnant, or breastfeeding.

psychosis, mania, bipolar illness,

(or a family history of) including:

had a reaction to other stimulant

past 14 days an anti-depression

medicine called a monoamine

have a history of drug abuse

oxidase inhibitor or MAOI.

of a total treatment program for

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have (or have a family history of) ever abused or been dependent on alcohol, prescription medicines or Who should not take Adderall $^{ ext{ iny B}}$ ?

> **Heart-Related Problems:** the arteries

> > alaucoma are very anxious, tense, or agitated

have hyperthyroidism

oxidase inhibitor or MAOI.

medicines Adderall® is not recommended for

 heart problems, heart defects, high blood pressure mental problems including

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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®. system stimulant prescription Your doctor will decide whether

Reference ID: 3378725

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

talking to your doctor first.

# How should Adderall® be taken?

- 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 contact Teva Pharmaceuticals at or two more doses may be taken
- without food.
- From time to time, your doctor may stop Adderall® treatment for a while to check ADHD symptoms.
- Your doctor may do regular checks of the blood, heart, and blood pressure while taking Adderall® Children should have their height and weight checked often while taking Adderall®. Adderall® treatment may be stopped if a problem is found during these check-ups.
- If you or your child take too much Adderall® or overdoses, call your doctor or poison control center right away, or get emergency treatment

What are possible side effects of Adderall®?

See "What is the most important information I should know about Adderall®?" for information on reported heart and mental problems.

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

- weight) in children seizures, mainly in patients with a
- history of seizures
- eyesight changes or blurred vision Common side effects include:
- headache
- stomach ache
- trouble sleeping
- decreased appetite
- nervousness
- dizziness

Adderall® may affect your or your child's ability to drive or do other dangerous activities.

Talk to your doctor if you or your child have side effects that are bothersome or do not go away.

This is not a complete list of possible side effects. Ask your doctor or pharmacist for more information.

effects to FDA at 1-800-FDA-1088.

# How should I store Adderall®?

- temperature, 20° to 25°C (68° to 77°F).
- Keep Adderall® and all medicines out of the reach of children.

General information about Adderall® Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Adderall® for a condition for which it was not prescribed. Do not give Adderall® to other people, even if Do not start any new medicine they have the same condition. It while taking Adderall® without 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 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 about Adderall® that was written for healthcare professionals. For more information about Adderall®, please

during the day, 4 to 6 hours apart. What are the ingredients in Adderall®? • Adderall® can be taken with or Active Ingredient: dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate.

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 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

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Rev. C 6/2013

# about side effects. You may report side

• Store Adderall® in a safe place at room

- - seizure medicines

anti-depression

including MAOIs

vour child take:

blood thinner medicines

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

What are possible side effects of Adderall®?

See "What is the most important information I should know about Adderall®?" for information on reported heart and mental problems

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

- seizures, mainly in patients with a history of seizures
- eyesight changes or blurred vision Common side effects include:

# headache

- stomach ache
- trouble sleeping
- decreased appetite
- nervousness
- dizziness

Adderall® may affect your or your child's ability to drive or do other dangerous activities.

Talk to your doctor if you or your child have side effects that are bothersome or do not go away.

This is not a complete list of possible side effects. Ask your doctor or pharmacist for more information.

## This label may not be the latest approved by FDA. For current labeling information, please visit https://www.fda.gov/drugsatfda

Especially tell your doctor if you or Call your doctor for medical advice X Especially tell your doctor for medical advice X Especially tell your doctor if you or Call your doctor for medical advice X about side effects. You may report side your child take:

# effects to FDA at 1-800-FDA-1088. How should I store Adderall®?

anti-depression

seizure medicines

including MAOIs

blood pressure medicines

blood thinner medicines

contain decongestants

stomach acid medicines

doctor and pharmacist

you or your child.

without food.

talking to your doctor first.

• cold or allergy medicines that

Know the medicines that you or

your child take. Keep a list of your

medicines with you to show your

Do not start any new medicine

while taking Adderall® without

How should Adderall® be taken?

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

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Adderall<sup>®</sup> can be taken with or

• From time to time, your doctor

a while to check ADHD symptoms.

pressure while taking Adderall®

Adderall®. Adderall® treatment may

See "What is the most important

information I should know about

Adderall®?" for information on

reported heart and mental problems

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weight) in children

history of seizures

headache

stomach ache

trouble sleeping

nervousness

dizziness

decreased appetite

dangerous activities.

slowing of growth (height and

• seizures, mainly in patients with a

eyesight changes or blurred vision

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child's ability to drive or do other

Talk to your doctor if you or your

child have side effects that are

This is not a complete list of possible

side effects. Ask vour doctor or

bothersome or do not go away.

pharmacist for more information.

Common side effects include:

during these check-ups.

treatment

prescribed. Your doctor

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

 Keep Adderall<sup>®</sup> 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 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 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®? • Adderall® can be taken with or Active Ingredient: dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate.

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

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

TEVA PHARMACEUTICALS USA What are possible side effects of Sellersville PA 18960 Adderall®?

Rev. C 6/2013

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<sup>®</sup> 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 • Take Adderall® exactly as information about Adderall®. If you 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 about Adderall® that was written for healthcare professionals. For more information about Adderall®, please contact Teva Pharmaceuticals at 1-888-838-2872.

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

may stop Adderall® treatment for **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 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 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 If you or your child take too much as a color additive.

Adderall® or overdoses, call your This Medication Guide has been doctor or poison control center approved by the U.S. Food and Drug right away, or get emergency

> TEVA PHARMACEUTICALS USA Sellersville PA 18960

> > Rev. C 6/2013

### MEDICATION GUIDE Adderall® (ADD-ur-all) Adderall® should not be taken if you or your child: See "What is the most important information I

(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 • 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 vour 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.

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

. Heart-Related Problems:

• increased blood pressure and heart rate

Tell your doctor if you or your child have any heart problems, heart defects, high blood pressure, or a family history of these problems. Your doctor should check you or your child carefully for heart problems before starting Adderall®

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

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

- 2. Mental (Psychiatric) Problems: All Patients
- new or worse behavior and thought problems new or worse bipolar illness
- new or worse aggressive behavior or hostility Children and Teenagers new psychotic symptoms (such as hearing)
- voices, believing things that are not true, are suspicious) or new manic symptoms Tell your doctor about any mental problems you

or your child have, or about a family history of suicide, bipolar illness, or depression. Call your doctor right away if you or your child

have any new or worsening mental symptoms or problems while taking Adderall®, especially seeing or hearing things that are not real, believing things that are not real, or are suspicious.

# What is Adderall®?

Adderall® is a central nervous system stimulant How should Adderall® be taken? prescription medicine. It is used for the treatment • Take Adderall® exactly as prescribed. Your 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 • Adderall® can be taken with or without food. 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®?

are very anxious, tense, or agitated

- have heart disease or hardening of the arteries
- have moderate to severe high blood pressure

are sensitive to, allergic to, or had a reaction to

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

Before starting Adderall® tell your or your

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

will need to be adjusted while taking Adderall®.

Your doctor will decide whether Adderall® can be

Especially tell your doctor if you or your child take:

cold or allergy medicines that contain

Do not start any new medicine while taking

doctor may adjust the dose until it is right for

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

• From time to time, your doctor may stop

Your doctor may do regular checks of the blood.

heart, and blood pressure while taking Adderall®

checked often while taking Adderall®. Adderall® treatment may be stopped if a problem is found

• If you or your child take too much Adderall $^{f @}$  or

overdoses, call your doctor or poison control center right away, or get emergency treatment.

Children should have their height and weight

Adderall® treatment for a while to check ADHD

Adderall® without talking to your doctor first.

anti-depression medicines including MAOIs

have hyperthyroidism

have a history of drug abuse

oxidase inhibitor or MAO

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.

seizure medicines

decongestants

you or your child

anart

symptoms

during these check-ups.

thyroid problems

test (FFG)

bipolar illness, or depression

less than 3 years old.

- slowing of growth (height and weight) in children have an eye problem called glaucoma
  - seizures, mainly in patients with a history of

What are possible side effects of Adderall®?

should know about Adderall®?" for information

eyesight changes or blurred vision

on reported heart and mental problems

Other serious side effects include:

### Common side effects include: an anti-depression medicine called a monoamine

- headache
- stomach ache
- trouble sleeping
- decreased appetite Adderall® is not recommended for use in children

  - nervousness
  - dizziness 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. seizures or have had an abnormal brain wave

# 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.

### you or your child take including prescription and General information about Adderall® nonprescription medicines, vitamins, and herbal

Medicines are sometimes prescribed for purposes supplements. Adderall® and some medicines may other than those listed in a Medication Guide. Do interact with each other and cause serious side not use Adderall<sup>®</sup> 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.

# What are the ingredients in Adderall®?

**Active Ingredient:** dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine Know the medicines that you or your child take. sulfate and amphetamine sulfate. Keep a list of your medicines with you to show

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

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

> TEVA PHARMACEUTICALS USA Sellersville, PA 18960

> > Rev. C 6/2013

# Reference ID: 3378725

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Guide that

# MEDICATION GUIDE Adderall® (ADD-ur-all)

(Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate and

Amphetamine Sulfate Tablets)

### ${f R}$ only Read the

Medication 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, fainting while taking Adderal $m l^{(B)}$ 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 or problems while taking Adderall® especially seeing or hearing things that are not real, believing things that are not real, or are suspicious.

# What is Adderall®?

Adderall® is a central nervous prescription system stimulant medicine. It is used for the treatment of Attention-Deficit Hyperactivity **Disorder (ADHD)**. Adderall® 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 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 $^{f @}$  should not be taken if you or your child:

- have heart disease or hardening of the arteries have moderate to severe
- blood pressure have hyperthyroidism
  - have an eye problem
  - glaucoma are very anxious, tense, or agitated

called

- 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<sup>®</sup> may not be right for you or your child. Before starting Adderall<sup>®</sup> tell your or your child's doctor about all health conditions (or a family history of) including: heart problems, heart defects, high blood pressure

- problems mental 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 $^{f @}$  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<sup>®</sup> 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.

This label may not be the latest approved by FDA. urrent labeling information, please visit https://www.fda.gov/drugs Especially tell your doctor if you or Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. 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. not start any new

Do not start any new medicine while taking Adderall® without talking to your doctor first. How should Adderall® be taken?

Adderall® exactly Take as Your doctor prescribed. may adjust the dose until it is right for

you or your child. Adderall® tablets are usually taken two to three times a day. The first dose is usually taken when you

first wake in the morning. One or two more doses may be taken during the day, 4 to 6 hours apart. Adderall<sup>®</sup> can be taken with or without food. From time to time, your doctor may stop Adderall<sup>®</sup> 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 $^{ ext{@}}$ . Adderall $^{ ext{@}}$  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

What are possible side effects of Adderall®?

right away, or get emergency

doctor or poison control center

Aluminum Lake as a color additive. The

contact

1-888-838-2872. dextroamphetamine amphetamine sulfate.

Teva

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

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

temperature, 20° to 25°C (68° to 77°F).

Keep Adderall<sup>®</sup> and all medicines

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 $^{ ext{@}}$  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

Pharmaceuticals

out of the reach of children.

**Inactive Ingredients:** colloidal silicon

dioxide, compressible sugar, corn starch, magnesium stearate, microcrystalline cellulose and saccharin sodium. 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

12.5 mg, 15 mg, 20 mg and 30 mg also contain FD&C Yellow #6 Aluminum Lake as a color additive. This Medication Guide has been approved by the U.S. Food and Drug

Administration. TEVA PHARMACEUTICALS USA

"What is the most important

information I should know about Adderall®?" for information 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

treatment.

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

# Sellersville, PA 18960 Rev. C 6/2013

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

single-entity amphetamine product combining the neutral sulfate salts of dextroamphetamine and

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
Amphetamine Aspartate Monohydrate Equivalent	1.25 mg <sup>a</sup>	1.875 mg <sup>b</sup>	2.5 mg <sup>c</sup>	3.125 mg <sup>d</sup>	3.75 mg <sup>e</sup>	5 mg <sup>f</sup>	7.5 mg <sup>9</sup>
Dextroamphetamine Sulfate, USP	1.25 mg	1.875 mg	2.5 mg	3.125 mg	3.75 mg	5 mg	7.5 mg
Amphetamine Sulfate, USP	1.25 mg	1.875 mg	2.5 mg	3.125 mg	3.75 mg	5 mg	7.5 mg
Total Amphetamine Base Equivalence	3.13 mg	4.7 mg	6.3 mg	7.8 mg	9.4 mg	12.6 mg	18.8 mg

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

### CLINICAL PHARMACOLOGY

release of these monoamines into the extraneuronal space.

release of these monoammes into the extraneuronal space.

Pharmacokinetics

Dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets contain d-amphetamine and -amphetamine salfs in the ratio of 3.1. Following administration of a single dose 10 or 30 mg of dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets to healthy volunteers under fasted conditions, peak plasma concentrations occurred approximately 3 hours post-dose for both d-amphetamine and l-amphetamine ame occurred approximately 3 hours post-dose for both d-amphetamine and l-amphetamine ame occurred approximately three-fold from 10 mg to 30 mg indicating dose-proportional pharmacokinetics.

The effect of food on the bioavailability of dextroamphetamine scharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets has not been studied.

Metabolism and Exception

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

minor inhibition of CVP1A2, 2D6, and 3A4 by one or more metabolites. However, due to the probability of auto-inhibition and the lack of information on the concentration of these metabolites relative to *in vivo* concentrations, no predications regarding the potential for amphetamine or its metabolists to inhibit the metabolism of other drugs by CVP isozymes *in vivo* can be made.

With normal urine pHs approximately half of an administered dose of amphetamine is recoverable in urine as derivatives of alpha-hydroxy-amphetamine and approximately another 30% to 40% of the dose is recoverable in urine as another and the second of the dose is recoverable in urine as a metabolization 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 dystruction have the potential to inhibit the elimination of amphetamine and result in prolonged exposures. In addition, drugs that affect urinary pH are known to alter the elimination of amphetamine and result in prolonged exposures. In addition, drugs that affect urinary pH are known to alter the elimination of amphetamine, and any decrease in amphetamine, see maphetamine, and that might occur due to drug interactions or genetic

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 Disorder (ADHD) psm-Ivo implies the presence of hyperactiveimpulsive 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-quirming, leaving seat; inappropriate 
running/climbing, difficulty with quiet activities; "on the go," excessive talking, bluring answers, can't walt turn 
intrusive. The Combined Type requires both inattentive and hyperactive-impulsive criteria to be met.

\*\*MADI antiquence and gastrointestinal alkalizing agents, such as antacids, should be avoided. 
and amphetamine molecule, thereby decreasing urinary excretion. Both groups of agents increase 
independent and experience the activity of tricyclic or sympathominetic agents; d-amphetamine with 
antidepressants, Tricyclic 
Antidepressants, Tricyclic 
Amphetamines may enhance the activity of tricyclic or sympathominetic agents; d-amphetamine with 
antidepressants, Tricyclic 
Antidepressants, Tricyclic 
Antidepressants, Tricyclic 
Antidepressants, as well as a metabolite of furazolidone, slow amphetamine metabolism. This slowing 
to a metabolite to fluoractive in the propo

Specific ethology 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.

Hermodynetamines may counteract the sedative effect of antihistamines. Anthippertensives
A

Need for Comprehensive Treatment Program

Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate and Amphetamine Sucharate, Amphetamine Aspartate, Dextroamphetamine Sucharate, Amphetamine Sucharate, Amphetamine Aspartate, Dextroamphetamine Sulfate Tablets are indicated as an integral part of a total treatment program for ADHD that may include of amphetamines, and can be used to treat amphetamine poisoning. Ethosoxximide

Ethosoxximide

Amphetamines and dealy intestinal absorption of ethosuximide. bits symptoms secondary to environmental factors and/or other primary psychiatric disorders, including thosis. Appropriate educational placement is essential and psychosocial intervention is often helpful. In remedial measures alone are insufficient, the decision to prescribe stimulant medication will depend in the physician's assessment of the chronicity and severity of the child's symptoms.

Long-term Use
The effectiveness of Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate
Tablets for long-term use has not been systematically evaluated in controlled
Amphetamine Sulfate Tablets for long-term use has not been systematically evaluated in controlled
trials. Therefore, the physician who elects to use Dextroamphetamine Saccharate, Amphetamine Aspartate,
Dextroamphetamine Sulfate Tablets for extended periods should periodically
Urinary excretion of amphetamines is increased, and efficant the extended periods should periodically
Urinary excretion of amphetamines is increased, and efficant the extended periods should periodically
Urinary excretion of amphetamines is increased, and efficant the extended periods should periodically

ranced arteriosclerosis, symptomatic cardiovascular disease, moderate to severe hyperte erthyroidism, known hypersensitivity or idiosyncrasy to the sympathomimetic amines, glaucoma. Agitated states.

Patients with a history of drug abuse.

Adults
Sudden deaths, stroke, and myocardial infarction have been reported in adults taking stimulant drugs at
usual doses for ADHD. Although the role of stimulants in these adult cases is also unknown, adults have a
greater likelihood than children of having serious structural cardiac abnormalities, 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 what seminated the properties of the properties of

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 suggests 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.

Amphetamine, in the enantiomer ratio present in dextroamphetamine saccharate, amphetamine aspartate, devarpament 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 speaker exponses in the in vitro sister chromatide exchange and chromosomal abertarian assays.

Amphetamine, in the enantiomer ratio present in dextroamphetamine saccharate, amphetamine aspartate, arrhythmia destroamphetamine suifate tablets (immediate-release) (d- to I- ratio of 3:1), was not classificated 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 nurse both of the Ames test, and equivocal response in the Ames test, and equivocal res

### Psychiatric Adverse Events

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

5 times the maximum recommended human dose of 30 mg/day on a mg/m² body surface area basis.

Prenancy

1 5 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
addition, each tablet contains the following inactive ingredients: colloidal silicon dioxide, compressible gar, corn starch, magnesium stearate, microcrystalline cellulose and saccharin sodium.
1e 5 mg, 7.5 mg and 10 mg also contain FD&C Blue ≠1 Aluminum Lake.
1e 12.5 mg, 15 mg and 30 mg also contain FD&C Yellow ≠6 Aluminum Lake.

LINICAL PHARMACOLOGY
1armacodynamics
1mphetamines are non-catecholamine sympathomimetic amines with CNS stimulant activity. The mode therapeutic action in Altention Deficit Hyperactivity Disorder (ADHD) is not known. Amphetamines are non-catecholamine sympathomimetic amines with CNS stimulant activity. The mode therapeutic action in Altention Deficit Hyperactivity Disorder (ADHD) is not known. Amphetamines are non-catecholamine sympathomimetic amines with CNS stimulant activity. The mode therapeutic action in Altention Deficit Hyperactivity Disorder (ADHD) is not known. Amphetamines are non-catecholamine sympathomimetic amines with CNS stimulant activity. The mode therapeutic action in Altention Deficit Hyperactivity Disorder (ADHD) is not known. Amphetamines are non-catecholamine sympathomimetic amines with CNS stimulant activity. The mode therapeutic action in Altention Deficit Hyperactivity Disorder (ADHD) is not known. Amphetamines are non-catecholamine sympathomimetic amines with CNS stimulant activity. The mode activity of the preservative neuron and increase the Section of the Aluminum Lake.

Selivers

# PRECAUTIONS

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.

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

Prescribers or other health professionals should inform patients, their families, and their caregivers about the benefits and risks associated with treatment with amphetamine or dextroamphetamine and should counsel them in its appropriate use. A patient Medication Guide is available for dextroamphetamine saccharate, 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.

<u>Urinary Acidifying Agents</u>
(ammonium chloride, sodium acid phosphate, etc.) increase the concentration of the ionized species of the

### Adreneraic Blockers Adrenergic blockers are inhibited by amphetamines.

Adlatinizing Agents
Gastrointestinal alkalinizing agents (sodium bicarbonate, etc.) increase absorption of amphetamines.
Coadministration of dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate balbets and gastrointestinal alkalizing agents, such as antacids, should be avoided.
Urinary alkalinizing agents (acetazolamide, some thiazides) increase the concentration of the non-ionized

### Amphetamines may antagonize the hypotensive effects of antihypertensives

# Urinary excretion of amphetamines is increased, and efficacy is reduced, by acidifying agents used in

Amphetamines may delay intestinal absorption of phenobarbital; coadministration of phenobarbital may produce a synergistic anticonvulsant action.

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

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 no adversely affect fertility or early embryonic development in the rat at doese of up to 20 mg/kg/day (approximate)

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

# ADVERSE REACTIONS

Allergic

DRUG ABUSE AND DEPENDENCE Dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets are a Schedule II controlled substance.

mphetamines have been extensively abused. Tolerance, extreme psychological dependence, and severe social sability have occurred. There are reports of patients who have increased the dosage to levels many times giper than recommended. Abrupt cessation following prolonged high dosage administration results in extreme lique and mental depression; changes are also noted on the sleep EEG. Manifestations of chronic intoxication

# Symptoms Manifestations of acute overdosage with amphetamines include restlessness, tremor, hyperreflexia, rapid respiration, confusion, assaultiveness, hallucinations, panic states, hyperpyrexia and rhabdomyolysis.

Cardiovascular effects include arrhythmias, hypertension or hypotension and circulatory collapse astrointestinal symptoms include nausea, vomiting, diarrhea, and abdominal cramps. Fatal poisoning is sually preceded by convulsions and coma.

Consult with a Certified Poison Control Center for up to date guidance and advice. Management of acute and amphetamine sulfate tablets. consum whin a certified Poison Control Center for up to date guidance and advice. Management of armphetamine introloxication 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. Actification 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

# eved. Chlorpromazine antagonizes the central stimulant effects of amphetamines and can be used to

DOSAGE AND ADMINISTRATION Regardless of indication, amphetamines should be administered at the lowest effective busselve, and on should be individually adjusted according to the therapeutic needs and response of the patient. Late evedoes should be avoided because of the resulting insomnia.

rements of 5 mg at weekly intervals until optimal response is obtained. Only in rare cases will it be cessary to exceed a total of 40 mg per day. Give first dose on awakening; additional doses (1 or 2) at ervals of 4 to 6 hours.

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.

### HOW SUPPLIED amine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate and Amphetamine Dextroampnetamille Saccharate, Amplica Sulfate Tablets are supplied as follows:

and a run solved in the fuller state decreases with 1/1/2. They are available in houses of the duthers. Blue, oval, flat-flated, beveled-edge tablet with 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 of 100 tablets.

TEVA PHARMACEUTICALS USA Sellersville, PA 18960

MEDICATION GUIDE

DEXTROAMPHETAMINE SACCHARATE, AMPHETAMINE ASPARTATE. DEXTROAMPHETAMINE SULFATE AND AMPHETAMINE SULFATE

(DEX-troe-am-FET-uh-meen SACK-uh-rate,

This label may not be the latest approved by FDA For current labeling information, please visit https://www.fda.gov/drugsatfda

Destroamphetamines Saccharate 125 mg 1875 mg 25 mg 3125 mg 375 mg 5 mg 75 mg 1 mg 4 mg/betamine Aspartate Monohydrate equivalent to 1.75 mg of Amphetamine Aspartate Monohydrate equivalent to 2.34 mg Amphetamine Aspartate Monohydrate equivalent to 1.55 mg of Amphetamine Aspartate Monohydrate equivalent to 1.55 mg of Amphetamine Aspartate Monohydrate equivalent to 4.6 mg Amphetamine Aspartate Monohydrate equivalent to 1.55 mg of Amphetamine Aspartate Monohydrate equivalent to 1.55 mg of Amphetamine Aspartate Monohydrate equivalent to 2.34 mg Amphetamine Aspartate Monohydrate equivalent to 3.51 mg Amphetamine Aspartate Monohydrate equivalent to 1.55 mg of Amphetamine Aspartate Monohydrate equivalent to 2.34 mg Amphetamine Aspartate Monohydrate equivalent to 3.51 mg Amphetamine Aspartate Monohydrate equivalent to 4.6 mg A Nonteratogenic Effects
Infants born to mothers dependent on amphetamines have an increased risk of premature delivery and low birth weight. Also, these infants may experience symptoms of withdrawal as demonstrated by dysphoria, including agitation, and significant lassitude.

all u each time you get a form. This Medication Guide does not take information. This Medication Guide does not take the place of talking to your doctor about you or your Usage in Nursing Mothers
Amphetamines are excreted in human milk. Mothers taking amphetamines should be advised to refrain from nursing.

Child's treatment with dextroamphetamine saccharate, Pediatric Use
Long-term effects of amphetamines in children have not been well established. Amphetamines are not

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

Your doctor should check you or your child carefully for heart problems before starting dextroamphetamine | • have moderate to severe high blood pressure saccharate, amphetamine aspartate, dextroamphetamine | • have hyperthyroidism sulfate and amphetamine sulfate tablets.

amphetamine aspartate, dextroamphetamine sulfate

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 amphetamine sulfate tablets.

# 2. Mental (Psychiatric) Problems:

- new or worse behavior and thought problems
- 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

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 Proton Pump Inhibitors

Pls 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, omerparable (40 mg once daily for 14 days), the median T<sub>max</sub> of 1-amphetamine was decreased by 1.25 hours (from 4 to 2.75 hours), and the median T<sub>max</sub> of 1-amphetamine was decreased by 2.5 hours (from 5.5 to 3 hours), compared to Adderall XR® (administered anone). The AUC and C<sub>max</sub> of each mobility were unaffected. Therefore, coadministration of dextroamphetamine such are available in bottles of 100 tablets.

25 mg

While taking dextroamphetamine amphetamine asparatate, dextroamphetamine sulfate tablets, especially seeing of 100 tablets.

25 mg

While taking dextroamphetamine amphetamine asparatate, dextroamphetamine sulfate tablets, especially seeing of 100 tablets.

26 mg

While taking dextroamphetamine amphetamine asparatate, dextroamphetamine sulfate tablets, especially seeing of 100 tablets.

27 mg

While taking dextroamphetamine amphetamine asparatate, dextroamphetamine sulfate and a multiple and a maphetamine amphetamine sulfate tablets, especially seeing of 100 tablets.

28 mg

While taking dextroamphetamine amphetamine asparatate, dextroamphetamine sulfate and a multiple amphetamine asparatate, dextroamphetamine sulfate tablets, especially seeing of 100 tablets.

29 mg

While taking dextroamphetamine amphetamine asparatate, dextroamphetamine sulfate and a full score on one side and two partial bisects on the other side debossed with 1 | 0. They are available in bottles of 100 tablets.

20 mg

While taking dextroamphetamine amphetamine amphetamine asparatate, dextroamphetamine sulfate and a full score on one side and two partial bisects on the other side debossed with 1 | 0. They are available in bottles of 100 tablets.

215 mg

While taking dextroamphetamine amphetamine amphetamine asparatate, dextroamphetamine sulfate tablets, especially seeing of 100 tablets.

215 mg

While taking dextroam while taking dextroamphetamine saccharate. of 100 tablets.
Peach, oval, flat-faced, beveled-edge tablet with two partial bisects on one side debossed with b over 973 and two partial bisects and a full score on the other side debossed with b over 974 and two partial bisects on one side debossed with b over 974 and two partial bisects on one side debossed with b over 974 and two partial bisects and a full score on the other side debossed with b over 974 and two partial bisects on one side debossed with b 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.

What are dextroamphetamine saccharate, 100 tablets.

Dispense in a tight, light-resistant container as defined in the USP, with a child-resistant closure (as required).

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

Teva Pharmaceuticals USA.

system stimulant prescription medicine. It is used  $\chi$ 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.

part of a total treatment program for ADHD that may  $\mid$   $\mid$  only 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.

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

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

amphetamine aspartate, dextroamphetamine sulfate

- have heart disease or hardening of the arteries
- have an eye problem called glaucoma
- Your doctor should check your or your child's are very anxious, tense, or agitated
  - an anti-depression medicine called a monoamine oxidase inhibitor or MAOI
  - stimulant medicines

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

- heart problems, heart defects, high blood pressure
- tics or Tourette's syndrome
- thyroid problems seizures or have had an abnormal brain wave test

planning to become pregnant, or breastfeeding. Can dextroamphetamine saccharate, amphetamine

Dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets should be used as a

Dextroamphetamine saccharate, amphetamine

family history of) ever abused or been dependent on alcohol, prescription medicines or street drugs.

- you or your child:

and amphetamine sulfate tablets?

- |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
  - are sensitive to, allergic to, or had a reaction to other

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

family history of) including:

- Tell your doctor about any mental problems you or your | mental problems including psychosis, mania, bipolar illness, or depression

  - Tell your doctor if you or your child are pregnant,

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

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, 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** 

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 nistory 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 blood pressure and heart rate regularly during

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:

new or worse bipolar illness

 new or worse aggressive behavior or hostility Children and Teenagers new psychotic symptoms (such as hearing voices,

new or worse behavior and thought problems

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?

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.

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

Tell your doctor if you or your child have (or have a

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

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

and amphetamine sulfate tablets?

- have an eye problem called glaucoma are very anxious, tense, or agitated 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 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 • 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 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?

Dextroamphetamine saccharate, amphetamine you or your child take including prescription and aspartate, dextroamphetamine sulfate and nonprescription medicines, vitamins, and herbal

amphetamine sulfate tablets are a central nervous supplements. Dextroamphetamine saccharate,

Tell your doctor about all of the medicines that

# Reference ID: 3378725

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HARATE,
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ROAMPHETAMINE
ATE AND AMPHETA
THE TABLETS

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## This label may not be the latest approved by FDA. For current labeling information, please visit https://www.fda.gov/drugsatfda

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 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.
- without food.
- 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 dextroamphetamine saccharate, amphetamine sulfate and 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 dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets or overdoses, call your doctor or poison control center right away, or get emergency treatment.

**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
- **F&BirZHEAS** C **ENAID!** 1931/3 708 11/2 Bts with a history of seizures

aspartate, Dextroamphetamine saccharate, amphetamine dextroamphetamine sulfate and amphetamine sulfate aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets may affect your or your child's ability to drive or do other dangerous activities. Talk to your doctor if you or your child have side effects that are bothersome or do not go away.

> This is not a complete list of possible side effects. Ask | • 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 temperature, 20° to 25°C (68° to 77°F).
- amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets and all | doctor first. 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 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, 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 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.

their height and weight checked often while taking saccharate, amphetamine aspartate, dextroamphetamine

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 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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X 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 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
- 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.

Do not start any new medicine while taking dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and • Keep dextroamphetamine saccharate, | aspartate, dextroamphetamine sulfate and • Keep dextroamphetamine saccharate, amphetamine sulfate tablets without talking to your

> 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.
- 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
- without food.
- check ADHD symptoms.
- blood, heart, and blood pressure while taking Teva Pharmaceuticals at 1-888-838-2872. dextroamphetamine saccharate, amphetamine Call your doctor for medical advice about side effects. 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 and 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 dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets or overdoses, call your doctor or poison control center right away, or get emergency treatment.

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

Dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets may affect your or your child's ability to drive or do other dangerous activities. Talk to your doctor if you or your child have side effects that are bothersome or do not go away.

This is not a complete list of possible side effects. Ask your doctor or pharmacist for more information.

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.

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 most important information about dextroamphetamine Dextroamphetamine saccharate, amphetamine saccharate, amphetamine aspartate, dextroamphetamine 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, 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 saccharate, amphetamine aspartate, dextroamphetamine • Your doctor may do regular checks of the sulfate and amphetamine sulfate tablets, please contact

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 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** 

### $\mathbb{R}$ 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 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 saccharate, dextroamphetamine amphetamine dextroamphetamine sulfate and aspartate. 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 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.

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

saccharate, Dextroamphetamine amphetamine dextroamphetamine sulfate aspartate. ampaterance Wifa 378 to a central nervous

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

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

Dextroamphetamine saccharate, amphetamine dextroamphetamine aspartate, and amphetamine sulfate tablets may be right for you or your child. Before starting dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate 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 (FFG)

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,

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amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets and some medicines may interact with each other and cause serious side effects. Sometimes the doses of other medicines will need to be adjusted while taking dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets.

Your doctor will decide whether dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets can be taken with other medicines.

# Especially tell your doctor if you or your child take:

- anti-depression medicines including MAOIs
- blood pressure medicines
- seizure medicines
- blood thinner medicines
- cold or allergy medicines that contain decongestants
- stomach acid medicines

Know the medicines that you or your child take. Keep a list of your medicines with you to show your doctor and pharmacist.

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

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

- Take dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets exactly as prescribed. Your doctor may adjust the dose until it is right for you or your child.
- Dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets are usually taken two to three times a day. The first dose is usually taken when you first wake in the morning. One or two more doses may be taken during the day, 4 to 6 hours apart.
- Dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets can be taken with or without food.
- From time to time, your doctor may stop dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets treatment for a while to check ADHD symptoms.
- Your doctor may do regular checks of the blood, heart, and blood pressure while taking dextroamphetamine saccharate, amphetamine dextroamphetamine sulfate aspartate. and amphetamine sulfate tablets. Children should have their height and weight checked often while taking dextroamphetamine saccharate. amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets. Dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets treatment may be stopped if a problem is found during these check-ups.
- If you or your child take too much dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets or overdoses, call your doctor or poison control center right away, or get emergency treatment.

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

See "What is the most important information I should know about dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets?" for information on reported heart and mental problems.

# Other serious side effects include:

- slowing of growth (height and weight) in children
- Reference and lysis 78 fights with a history of seizures

• eyesight changes or blurred vision

# Common side effects include:

- headache
- stomach ache
- trouble sleeping
- decreased appetite
- nervousness
- dizziness

Dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets may affect your or your child's ability to drive or do other dangerous activities.

Talk to your doctor if you or your child have side effects that are bothersome or do not go away.

This is not a complete list of possible side effects. Ask your doctor or pharmacist for more information.

How should I store dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets?

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

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

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets for a condition for which it was not prescribed. Do not give dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets to other people, even if they have the same condition. It may harm them and it is against the law. This Medication Guide summarizes the most important information about dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets that was written for healthcare professionals. For additional information on dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets, please contact Teva Pharmaceuticals at 1-888-838-2872.

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

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

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

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

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

# TEVA PHARMACEUTICALS USA

Sellersville, PA 18960

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signature.	

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