DEXTROAMPHETAMINE SACCHARATE, AMPHETAMINE ASPARTATE, DEXTROAMPHETAMINE SULFATE AND AMPHETAMINE SULFATE- dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablet
Zydus Pharmaceuticals (USA) Inc.

Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate and Amphetamine Sulfate Tablet

AMPHETAMINES HAVE A HIGH POTENTIAL FOR ABUSE. ADMINISTRATION OF AMPHETAMINES FOR PROLONGED PERIODS OF TIME MAY LEAD TO DRUG DEPENDENCE AND MUST BE AVOIDED. PARTICULAR ATTENTION SHOULD BE PAID TO THE POSSIBILITY OF SUBJECTS OBTAINING AMPHETAMINES FOR NON-THERAPEUTIC USE OR DISTRIBUTION TO OTHERS, AND THE DRUGS SHOULD BE PRESCRIBED OR DISPENSED SPARINGLY.

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

DESCRIPTION

A single-entity amphetamine product combining the neutral sulfate salts of dextroamphetamine and amphetamine, with the dextro isomer of amphetamine saccharate and d, l-amphetamine aspartate monohydrate.

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	1.875 mg	2.5 mg	3.125 mg	3.75 mg	5 mg	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 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

* 1.25 mg of Amphetamine Aspartate Monohydrate equivalent to 1.17 mg Amphetamine Aspartate (Anhydrous) as supplied
1.875 mg of Amphetamine Aspartate Monohydrate equivalent to 1.755 mg Amphetamine Aspartate (Anhydrous) as supplied
2.5 mg of Amphetamine Aspartate Monohydrate equivalent to 2.34 mg Amphetamine Aspartate (Anhydrous) as supplied
3.125 mg of Amphetamine Aspartate Monohydrate equivalent to 2.925 mg Amphetamine Aspartate (Anhydrous) as supplied
3.75 mg of Amphetamine Aspartate Monohydrate equivalent to 3.51 mg Amphetamine Aspartate (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 7.02 mg Amphetamine Aspartate (Anhydrous) as supplied

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

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.

CLINICAL PHARMACOLOGY

Pharmacodynamics

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

Pharmacokinetics

Dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets contain d-amphetamine and l-amphetamine salts in the ratio of 3:1. Following administration of a single dose 10 or 30 mg of dextroamphetamine saccharate, amphetamine 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. The mean elimination half-life ($t_{1/2}$) for d-amphetamine was shorter than the $t_{1/2}$ of the l-isomer (6.77 to 11 hours vs. 11.5 to 13.8 hours). The PK parameters (Cmax, AUC_{0-inf}) of d- and l-amphetamine increased approximately three-fold from 10 mg to 30 mg indicating dose-proportional pharmacokinetics.

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

Metabolism and Excretion

Amphetamine is reported to be oxidized at the 4 position of the benzene ring to form 4-hydroxyamphetamine, or on the side chain or β carbon 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.

Amphetamine is known to inhibit monoamine oxidase, whereas the ability of amphetamine and its metabolites to inhibit various P450 isozymes and other enzymes has not been adequately elucidated. *In vitro* experiments with human microsomes indicate minor inhibition of CYP2D6 by amphetamine and minor inhibition of CYP1A2, 2D6, and 3A4 by one or more metabolites. However, due to the probability of anti-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 metabolites to inhibit the metabolism of other drugs by CYP isozymes *in vivo* can be made.

With normal urine pHs approximately half of an administered dose of amphetamine is recoverable in urine as derivatives of alpha-hydroxy-amphetamine and approximately another 30% to 40% of the dose is recoverable in urine as amphetamine itself. Since amphetamine has a pKa of 9.9, urinary recovery of amphetamine is highly dependent on pH and urine flow rates. Alkaline urine pHs result in less ionization and reduced renal elimination, and acidic pHs and high flow rates result in increased renal elimination with clearances greater than glomerular filtration rates, indicating the involvement of active secretion. Urinary recovery of amphetamine has been reported to range from 1% to 75%, depending on urinary pH, with the remaining fraction of the dose hepatically metabolized. Consequently, both hepatic and renal dysfunction have the potential to inhibit the elimination of amphetamine and result in prolonged exposures. In addition, drugs that affect urinary pH are known to alter the elimination of amphetamine, and any decrease in amphetamine's metabolism that might occur due to drug interactions or genetic polymorphisms is more likely to be clinically significant when renal elimination is decreased (see **PRECAUTIONS**).

INDICATIONS AND USAGE

Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate and Amphetamine Sulfate Tablets are indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) and Narcolepsy.

Attention Deficit Hyperactivity Disorder (ADHD)

A diagnosis of Attention Deficit Hyperactivity Disorder (ADHD; DSM-IV®) implies the presence of hyperactive-impulsive or inattentive symptoms that caused impairment and were present before age 7 years. The symptoms must cause clinically significant impairment, e.g., in social, academic, or occupational functioning, and be present in two or more settings, e.g., school (or work) and at home. The symptoms must not be better accounted for by another mental disorder. For the Inattentive Type, at least six of the following symptoms must have persisted for at least 6 months: lack of attention to details/careless mistakes; lack of sustained attention; poor listener; failure to follow through on tasks; poor organization; avoids tasks requiring sustained mental effort; loses things; easily distracted; forgetful. For the Hyperactive-Impulsive Type, at least six of the following symptoms must have persisted for at least 6 months: fidgeting/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.

Special Diagnostic Considerations

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

Need for Comprehensive Treatment Program

Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate and Amphetamine Sulfate Tablets are indicated as an integral part of a total treatment program for ADHD that may include other measures (psychological, educational, social) for patients with this syndrome. Drug treatment may not be indicated for all children with this syndrome. Stimulants are not intended for use in the child who exhibits symptoms secondary to environmental factors and/or other primary psychiatric disorders, including psychosis. Appropriate educational placement is essential and psychosocial intervention is often helpful. When remedial measures alone are insufficient, the decision to prescribe stimulant medication will depend upon 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 and 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 and Amphetamine Sulfate Tablets for extended periods should periodically re-evaluate the long-term usefulness of the drug for the individual patient.

CONTRAINDICATIONS

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

Agitated states.

Known hypersensitivity or idiosyncrasy to amphetamine.

Patients with a history of drug abuse.

In patients known to be hypersensitive to amphetamine, or other components of Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate and Amphetamine Sulfate Tablets. Hypersensitivity reactions such as angioedema and anaphylactic reactions have been reported in patients treated with other amphetamine products [see **ADVERSE REACTIONS**].

Patients taking monoamine oxidase inhibitors (MAOIs), or within 14 days of stopping MAOIs (including MAOIs such as linezolid or intravenous methylene blue), because of an increased risk of hypertensive crisis [see **WARNINGS** and **DRUG INTERACTIONS**].

WARNINGS

Serious Cardiovascular Events

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

Children and Adolescents

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

Adults

Sudden deaths, stroke, and myocardial infarction have been reported in adults taking stimulant drugs at usual doses for ADHD. Although the role of stimulants in these adult cases is also unknown, adults have a greater likelihood than children of 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**).

Hypertension and Other Cardiovascular Conditions

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

Assessing Cardiovascular Status in Patients Being Treated With Stimulant Medications

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

Psychiatric Adverse Events

Preexisting Psychosis

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

Bipolar Illness

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

Emergence of New Psychotic or Manic Symptoms

Treatment-emergent psychotic or manic symptoms, e.g., hallucinations, delusional thinking, or mania in children and adolescents without prior history of psychotic illness or mania can be caused by stimulants at usual doses. If such symptoms occur, consideration should be given to a possible causal role of the stimulant, and discontinuation of treatment may be appropriate. In a pooled analysis of multiple short-term, placebo-controlled studies, such symptoms occurred in about 0.1% (4 patients with events out of 3482 exposed to methylphenidate or amphetamine for several weeks at usual doses) of stimulant-treated patients compared to 0 in placebo-treated patients.

Aggression

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

Long-Term Suppression of Growth

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 (i.e., treatment for 7 days per week throughout the year) have a temporary slowing in growth rate (on average, a total of about 2 cm less growth in height and 2.7 kg less growth in weight over 3 years), without evidence of growth rebound during this period of development. Published data are inadequate to determine whether chronic use of amphetamines may cause a similar suppression of growth, however, it is anticipated that they will likely have this effect as well. Therefore, growth should be monitored during treatment with stimulants, and patients who are not growing or gaining weight as expected may need to have their treatment interrupted.

Seizures

There is some clinical evidence that stimulants may lower the convulsive threshold in patients with prior history of seizure, in patients with prior EEG abnormalities in absence of 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.

Peripheral Vasculopathy, Including Raynaud's Phenomenon

Stimulants, including dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets, used to treat ADHD are associated with peripheral vasculopathy, including Raynaud's phenomenon. Signs and symptoms are usually intermittent and mild; however, very rare sequelae include digital ulceration and/or soft tissue breakdown. Effects of peripheral vasculopathy, including Raynaud's phenomenon, were observed in postmarketing reports at different times and at therapeutic doses in all age groups throughout the course of treatment. Signs and symptoms generally improve after reduction in dose or discontinuation of drug. Careful observation for digital changes is necessary during treatment with ADHD stimulants. Further clinical evaluation (e.g., rheumatology referral) may be appropriate for certain patients.

Serotonin Syndrome

Serotonin syndrome, a potentially life-threatening reaction, may occur when amphetamines are used in combination with other drugs that affect the serotonergic neurotransmitter system such as monoamine oxidase inhibitors (MAOIs), selective serotonin reuptake inhibitors (SSRIs), serotonin norepinephrine reuptake inhibitors (SNRIs), triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, tryptophan, buspirone, and St. John's Wort [see **DRUG INTERACTIONS**]. Amphetamines and amphetamine derivatives are known to be metabolized, to some degree, by cytochrome P450 2D6 (CYP2D6) and display minor inhibition of CYP2D6 metabolism [see **CLINICAL PHARMACOLOGY**]. The potential for a pharmacokinetic interaction exists with the coadministration of CYP2D6 inhibitors which may increase the risk with increased exposure to dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets. In these situations, consider an alternative monoamine releasing or an alternative drug that does not inhibit CYP2D6 [see **DRUG INTERACTIONS**].

Serotonin syndrome symptoms may include mental status changes (e.g., agitation, hallucinations, delirium, and coma), autonomic instability (e.g., tachycardia, labile blood pressure, dizziness, diaphoresis, flushing, hyperthermia), neuromuscular symptoms (e.g., tremor, rigidity, myoclonus, hyperreflexia, incoordination), seizures, and/or gastrointestinal symptoms (e.g., nausea, vomiting, diarrhea).

Concomitant use of dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets with MAOI drugs is contraindicated [see **CONTRAINDICATIONS**].

Discontinue treatment with dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets and any concomitant serotonergic agents immediately if the above symptoms occur, and initiate supportive symptomatic treatment. If concomitant use of dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets with other serotonergic drugs or CYP2D6 inhibitors is clinically warranted, initiate dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets with lower doses, monitor patients for the emergence of serotonin syndrome during drug initiation or titration, and inform patients of the increased risk for serotonin syndrome.

Visual Disturbance

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

PRECAUTIONS

General

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

Tics

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

Information for Patients

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

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

Circulation Problems in Fingers and Toes [Peripheral Vasculopathy, Including Raynaud's Phenomenon]

- Instruct patients beginning treatment with dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets about the risk of peripheral vasculopathy, including Raynaud's phenomenon, and associated signs and symptoms: fingers or toes may feel numb, cool, painful, and/or may change color from pale to blue to red.
- Instruct patients to report to their physician any new numbness, pain, skin color change, or sensitivity to temperature in fingers or toes.
- **Instruct patients to call their physician immediately with any signs of unexplained wounds appearing on fingers or toes while taking dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets.**
- Further clinical evaluation (e.g., rheumatology referral) may be appropriate for certain patients.

Drug Interactions

Acidifying Agents

Lower blood levels and efficacy of amphetamines. Increase dose based on clinical response. Examples of acidifying agents include gastrointestinal acidifying agents (e.g., guanethidine, reserpine, glutamine acid HCl, ascorbic acid) and urinary acidifying agents (e.g., ammonium chloride, sodium acid phosphate, methenamine salts).

Adrenergic Blockers

Adrenergic blockers are inhibited by amphetamines.

Alkalinizing Agents

Increase blood levels and potentiate the action of amphetamine. Co-administration of dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets and gastrointestinal alkalinizing agents should be avoided. Examples of alkalinizing agents include gastrointestinal alkalinizing agents (e.g., sodium bicarbonate) and urinary alkalinizing agents (e.g. acetazolamide, some thiazides).

Tricyclic Antidepressants

May enhance the activity of tricyclic or sympathomimetic agents causing striking and sustained increases in the concentration of d-amphetamine in the brain; cardiovascular effects can be potentiated. Monitor frequently and adjust or use alternative therapy based on clinical response. Examples of tricyclic antidepressants include desipramine, protriptyline.

CYP2D6 Inhibitors

The concomitant use of dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets and CYP2D6 inhibitors may increase the exposure of dextroamphetamine sulfate and amphetamine sulfate tablets. Consider a lower dose of dextroamphetamine sulfate tablets compared to the use of the drug alone and increase the risk of serotonin syndrome. Initiate with lower doses and monitor patients for signs and symptoms of serotonin syndrome particularly during dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets initiation and after a dosage increase. If serotonin syndrome occurs, discontinue dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets and the CYP2D6 inhibitor [see **WARNINGS, OVERDOSAGE**]. Examples of CYP2D6 inhibitors include paroxetine and fluoxetine (also serotonergic drugs), quinidine, ritonavir.

Serotonergic Drugs

The concomitant use of dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets and serotonergic drugs increases the risk of serotonin syndrome. Initiate with lower doses and monitor patients for signs and symptoms of serotonin syndrome, particularly during dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets initiation or dosage increase. If serotonin syndrome occurs, discontinue dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets and the concomitant serotonergic drug(s) [see **WARNINGS**, and **PRECAUTIONS**]. Examples of serotonergic drugs include selective serotonin reuptake inhibitors (SSRI), serotonin norepinephrine reuptake inhibitors (SNRI), triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, tryptophan, buspirone, St. John's Wort.

MAO Inhibitors

Concomitant use of MAOIs and CNS stimulants can cause hypertensive crisis. Potential outcomes include death, stroke, myocardial infarction, aortic dissection, ophthalmological complications, eclampsia, pulmonary edema, and renal failure. Do not administer dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets concomitantly or within 14 days after discontinuing MAOI [see **CONTRAINDICATIONS** and **WARNINGS**]. Examples of MAOIs include selegiline, tranylcypromine, isocarboxazid, phenelzine, linezolid, methylene blue.

Antihistamines

Amphetamines may counteract the sedative effect of antihistamines.

Antihypertensives

Amphetamines may antagonize the hypotensive effects of antihypertensives.

Chlorpromazine

Chlorpromazine blocks dopamine and norepinephrine receptors, thus inhibiting the central stimulant effects of amphetamines, and can be used to treat amphetamine poisoning.

Ethosuximide

Amphetamines may delay intestinal absorption of ethosuximide.

Haloperidol

Haloperidol blocks dopamine receptors, thus inhibiting the central stimulant effects of amphetamines.

Lithium Carbonate

The anorectic and stimulatory effects of amphetamines may be inhibited by lithium carbonate.

Meperidine

Amphetamines potentiate the analgesic effect of meperidine.

Methenamine Therapy

Urinary excretion of amphetamines is increased, and efficacy is reduced, by acidifying agents used in methenamine therapy.

Norepinephrine

Amphetamines enhance the adrenergic effect of norepinephrine.

Phenobarbital

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

Phenytoin

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

Propoxyphene

In cases of propoxyphene overdosage, amphetamine CNS stimulation is potentiated and fatal convulsions can occur.

Proton Pump Inhibitors

Time to maximum concentration (Tmax) of amphetamine is decreased compared to when administered alone. Monitor patients for changes in clinical effect and adjust therapy based on clinical response. An example of a proton pump inhibitor is omeprazole.

Veratrum Alkaloids

Amphetamines inhibit the hypotensive effect of veratrum alkaloids.

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.

Carcinogenesis Mutagenesis and Impairment of Fertility

No evidence of carcinogenicity was found in studies in which dl-amphetamine (enantiomer ratio of 1:1) was administered to mice and rats in the diet for 2 years at doses of up to 30 mg/kg/day in male mice, 19 mg/kg/day in 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 area basis.

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

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

Pregnancy

Teratogenic Effects

Pregnancy Category C

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

A number of studies in rodents indicate that prenatal or early postnatal exposure to amphetamine (d- or dl-), at doses similar to those used clinically, can result in long-term neurochemical and behavioral 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 severe congenital bony deformity, trachea-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

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.

Usage in Nursing Mothers

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

Pediatric Use

Long-term effects of amphetamines in children have not been well established. Amphetamines are not recommended for use in children under 3 years of age with Attention Deficit Hyperactivity Disorder described under **INDICATIONS AND USAGE**.

Geriatric Use

Dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets have not been studies in the geriatric population.

ADVERSE REACTIONS

Cardiovascular

Palpitation, tachycardia, elevation of blood pressure, sudden death, myocardial infarction. There have been isolated reports of cardiomyopathy associated with chronic amphetamine use.

Central Nervous System

Psychotic episodes at recommended doses, overstimulation, restlessness, irritability, euphoria, dyskinesia, dysphoria, depression, tremor, tics, aggression, anger, logorrhea, dermatillomania.

Eye Disorders

Vision blurred, mydriasis.

Gastrointestinal

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

Allergic

Urticaria, rash, hypersensitivity reactions including angioedema and anaphylaxis. Serious skin rashes, including Stevens-Johnson syndrome and toxic epidermal necrolysis have been reported.

Endocrine

Impotence, changes in libido, frequent or prolonged erections.

Skin

Alopecia.

Musculoskeletal

Rhabdomyolysis.

DRUG ABUSE AND DEPENDENCE

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

Amphetamines have been extensively abused. Tolerance, extreme psychological dependence, and severe social disability have occurred. There are reports of patients who have increased the dosage to levels many times higher than recommended. Abrupt cessation following prolonged high dosage 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, marked insomnia, irritability, hyperactivity, and personality changes. The most severe manifestation of chronic intoxication is psychosis, often clinically indistinguishable from schizophrenia.

OVERDOSAGE

Manifestations of amphetamine overdosage include restlessness, tremor, hyperreflexia, rapid respiration, confusion, assaultiveness, hallucinations, panic states, hyperpyrexia and rhabdomyolysis. Fatigue and depression usually follow the central nervous system stimulation. Serotonin syndrome has also been reported.

Cardiovascular 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.

Treatment

Consult with a Certified Poison Control Center for up to date guidance and advice.

DOSAGE AND ADMINISTRATION

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

Attention Deficit Hyperactivity Disorder

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

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

Where possible, drug administration should be interrupted occasionally to determine if there is a recurrence of behavioral symptoms sufficient to require continued therapy.

Narcolepsy

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

Narcolepsy seldom occurs in children under 12 years of age; however, when it does, dextroamphetamine sulfate may be used. The suggested initial dose for patients aged 6 to 12 is 5 mg daily; daily dose may be raised in increments of 5 mg at weekly intervals until optimal response is obtained. In patients 12 years of age and older, start with 10 mg daily; daily dosage may be raised in increments of 10 mg at weekly intervals until optimal response is obtained. If bothersome adverse reactions appear (e.g., 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

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

5 mg: Blue, oval, biconvex tablet, quadrisect on one side and "N" over "950" on the other side.

NDC 68382-950-01……Bottles of 100 Tablets

7.5 mg: Blue, round, flat- faced, beveled-edge tablet, quadrisect on one side and "N" over "951" on the other side.

NDC 68382-951-01……Bottles of 100 Tablets

10 mg: Blue, oval, flat-faced, beveled- edge tablet, quadrisect on one side and "N" over 952" on the other side.

NDC 68382-952-01……Bottles of 100 Tablets

12.5 mg: Peach, oval, biconvex tablet, quadrisect on one side and N" over "953" on the other side.

NDC 68382-953-01……Bottles of 100 Tablets

15 mg: Peach, round, flat-faced, beveled-edge tablet, quadrisect on one side and "N" over 954" on the other side.

NDC 68382-954-01……Bottles of 100 Tablets

20 mg: Peach, oval, flat-faced, beveled-edge tablet, quadrisect on one side with "N" over" 955" on the other side.

NDC 68382-955-01……Bottles of 100 Tablets

30 mg: Peach, oval, biconvex tablet quadrisect on one side with "N" over "956" on the other side.

NDC 68382-956-01……Bottles of 100 Tablets

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

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

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

All brand names listed are the registered trademarks of their respective owners and are not trademarks of Neuber Pharmaceuticals (USA) LLC.

DEA Order Form Required.

Manufactured By:

Neuber Pharmaceuticals USA LLC

St. Louis, MO 63044

Distributed by:

Zydus Pharmaceuticals USA Inc.

Pennington, NJ 08534

2055162

10/2017

SPL MEDGUIDE

MEDICATION GUIDE

DEXTROAMPHETAMINE SACCHARATE, AMPHETAMINE ASPARTATE, DEXTROAMPHETAMINE SULFATE AND AMPHETAMINE SULFATE TABLETS CII
(*DEX-tro-am-FET-ah-meen SACR-ah-rate, am-FET-ah-meen ass-PAR-tate, DEX-tro-am-FET-ah-meen SULL-fate, and am-FET-ah-meen SULL-fate*)

Rx only

Read the Medication Guide that comes with dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets before you or your child starts taking it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your doctor about you or your child's treatment with dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets.

What is the most important information I should know about dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets?
The following have been reported with use of dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets and other stimulant medicines.
1. Heart Related Problems:
- **sudden death in patients who have heart problems or heart defects**
- **stroke and heart attack in adults**
- **increased blood pressure and heart rate**

Tell your doctor if you or your child have any heart problems, heart defects, high blood pressure, or a family history of these problems.
Your doctor should check you or your child carefully for heart problems before starting dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets.
Your doctor should check you or your child's blood pressure and heart rate regularly during treatment with dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets.
Call your doctor right away if you or your child have any signs of heart problems such as chest pain, shortness of breath, or fainting while taking dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets.
2. Mental (Psychiatric) Problems:
All Patients
- **new or worse behavior and thought problems**
- **new or worse bipolar illness**
- **new or worse aggressive behavior or hostility**

Children and Teenagers
- **new psychotic symptoms (such as hearing voices, believing things that are not true, are suspicious) or new manic symptoms**

Tell your doctor about any mental problems you or your child have, or about a family history of suicide, bipolar illness, or depression.
Call your doctor right away if you or your child have any new or worsening mental symptoms or problems while taking dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets, especially seeing or hearing things that are not real, believing things that are not real, or are suspicious.
3. Circulation Problems in Fingers and Toes [Peripheral Vasculopathy, Including Raynaud's Phenomenon]:
- Fingers or toes may feel numb, cool, painful and/or may change color from pale, to blue, to red

Tell your doctor if you have or your child has numbness, pain, skin color change, or sensitivity to temperature in your fingers or toes.
Call your doctor right away if you have or your child has any signs of unexplained wounds appearing on fingers or toes while taking dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets.

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

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

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

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

Dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets are a federally controlled substance (CII) because it can be abused or lead to dependence. Keep dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets in a safe place to prevent misuse and abuse. Selling or giving away dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets may harm others, and is against the law. Tell your doctor if you or your child have (or have a family history of) ever abused or been dependent on alcohol, prescription medicines or street drugs.

Who should not take dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets?

Dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets should not be taken if you or your child:
- have heart disease or hardening of the arteries
- have moderate to severe high blood pressure
- have hyperthyroidism
- have an eye problem called glaucoma
- are very anxious, tense, or agitated
- have a history of drug abuse
- are taking or have taken within the past 14 days an anti-depression medicine called a monoamine oxidase inhibitor or MAOI
- are sensitive to, allergic to, or had a reaction to other stimulant medicines

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

Dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets may not be right for you or your child. Before starting dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets tell your or your child's doctor about all health conditions (or a family history of) including:
- heart problems, heart defects, high blood pressure
- mental problems including psychosis, mania, bipolar illness, or depression
- tics or Tourette's syndrome
- liver or kidney problems
- thyroid problems
- seizures or have had an abnormal brain wave test (EEG)
- circulation problems in fingers and toes

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

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

Tell your doctor about all of the medicines that you or your child take including prescription and nonprescription medicines, vitamins, and herbal supplements. Dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets and some medicines may interact with each other and cause serious side effects. Sometimes the doses of other medicines will need to be adjusted while taking dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets.

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

Especially tell your doctor if you or your child take:
- anti-depression medicines including MAOIs
- blood pressure medicines
- seizure medicines
- blood thinner medicines
- cold or allergy medicines that contain decongestants
- stomach acid medicines

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

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

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

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

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

Other serious side effects include:
- slowing of growth (height and weight) in children
- seizures, mainly in patients with a history of seizures
- eyesight changes or blurred vision
- Serotonin syndrome. A potentially life-threatening problem called serotonin syndrome can happen when medicines such as dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets are taken with certain other medicines. Symptoms of serotonin syndrome may include:
  - agitation, hallucinations, coma or other changes in mental status
  - problems controlling your movements or muscle twitching
  - fast heartbeat
  - high or low blood pressure
  - sweating or fever
  - nausea or vomiting
  - diarrhea
  - muscle stiffness or tightness

Common side effects include:
- stomach ache
- decreased appetite
- 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.

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

How should I store 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 roomtemperature, 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 Zydus Pharmaceuticals at 1-877-932-8779.

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

Active Ingredients: dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, USP, amphetamine sulfate, USP

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

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

Manufactured By:

Neuber Pharmaceuticals USA LLC

St. Louis, MO 63044

Distributed by:

Zydus Pharmaceuticals USA Inc.

Pennington, NJ 08534

PRINCIPAL DISPLAY PANEL - 5 mg 100 Count Bottle

5 mg 100 Count Bottle Label

NDC 68382-950-01 **CII**
Dextroamphetamine Saccharate,
Amphetamine Aspartate,
Dextroamphetamine Sulfate and
Amphetamine Sulfate Tablets
(Mixed Salts of a Single Entity Amphetamine Product)
5 mg
PHARMACIST: DISPENSE THE ACCOMPANYING MEDICATION GUIDE TO EACH PATIENT
Zydus Pharmaceuticals
100 TABLETS
Rx Only

PRINCIPAL DISPLAY PANEL - 7.5 mg 100 Count Bottle

7.5 mg 100 Count Bottle Label

NDC 68382-951-01 **CII**
Dextroamphetamine Saccharate,
Amphetamine Aspartate,
Dextroamphetamine Sulfate and
Amphetamine Sulfate Tablets
(Mixed Salts of a Single Entity Amphetamine Product)
7.5 mg
PHARMACIST: DISPENSE THE ACCOMPANYING MEDICATION GUIDE TO EACH PATIENT
Zydus Pharmaceuticals
100 TABLETS
Rx Only

PRINCIPAL DISPLAY PANEL - 10 mg 100 Count Bottle

10 mg 100 Count Bottle Label

NDC 68382-952-01 **CII**
Dextroamphetamine Saccharate,
Amphetamine Aspartate,
Dextroamphetamine Sulfate and
Amphetamine Sulfate Tablets
(Mixed Salts of a Single Entity Amphetamine Product)
10 mg
PHARMACIST: DISPENSE THE ACCOMPANYING MEDICATION GUIDE TO EACH PATIENT
Zydus Pharmaceuticals
100 TABLETS
Rx Only

PRINCIPAL DISPLAY PANEL - 12.5 mg 100 Count Bottle

12.5 mg 100 Count Bottle Label

NDC 68382-953-01 **CII**
Dextroamphetamine Saccharate,
Amphetamine Aspartate,
Dextroamphetamine Sulfate and
Amphetamine Sulfate Tablets
(Mixed Salts of a Single Entity Amphetamine Product)
12.5 mg
PHARMACIST: DISPENSE THE ACCOMPANYING MEDICATION GUIDE TO EACH PATIENT
Zydus Pharmaceuticals
100 TABLETS
Rx Only

PRINCIPAL DISPLAY PANEL - 15 mg 100 Count Bottle

15 mg 100 Count Bottle Label

NDC 68382-954-01 **CII**
Dextroamphetamine Saccharate,
Amphetamine Aspartate,
Dextroamphetamine Sulfate and
Amphetamine Sulfate Tablets
(Mixed Salts of a Single Entity Amphetamine Product)
15 mg
PHARMACIST: DISPENSE THE ACCOMPANYING MEDICATION GUIDE TO EACH PATIENT
Zydus Pharmaceuticals
100 TABLETS
Rx Only

PRINCIPAL DISPLAY PANEL - 20 mg 100 Count Bottle

20 mg 100 Count Bottle Label

NDC 68382-955-01 **CII**
Dextroamphetamine Saccharate,
Amphetamine Aspartate,
Dextroamphetamine Sulfate and
Amphetamine Sulfate Tablets
(Mixed Salts of a Single Entity Amphetamine Product)
20 mg
PHARMACIST: DISPENSE THE ACCOMPANYING MEDICATION GUIDE TO EACH PATIENT
Zydus Pharmaceuticals
100 TABLETS
Rx Only

PRINCIPAL DISPLAY PANEL - 30 mg 100 Count Bottle

30 mg 100 Count Bottle Label

NDC 68382-956-01 **CII**
Dextroamphetamine Saccharate,
Amphetamine Aspartate,
Dextroamphetamine Sulfate and
Amphetamine Sulfate Tablets
(Mixed Salts of a Single Entity Amphetamine Product)
30 mg
PHARMACIST: DISPENSE THE ACCOMPANYING MEDICATION GUIDE TO EACH PATIENT
Zydus Pharmaceuticals
100 TABLETS
Rx Only

DEXTROAMPHETAMINE SACCHARATE, AMPHETAMINE ASPARTATE, DEXTROAMPHETAMINE SULFATE AND AMPHETAMINE SULFATE

dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:68382-950
Route of Administration	ORAL	**DEA Schedule**	CII

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AMPHETAMINE SULFATE (UNII: 6DPSN7K6AR) (AMPHETAMINE - UNII:DE08037KNI)	AMPHETAMINE SULFATE	1.25 mg
AMPHETAMINE ASPARTATE MONOHYDRATE (UNII: O42PWL3O1A) (AMPHETAMINE - UNII:CK6CO1Q1Z7)	AMPHETAMINE ASPARTATE MONOHYDRATE	1.25 mg
DEXTROAMPHETAMINE SULFATE (UNII: 1TS9I1G57N) (DEXTROAMPHETAMINE - UNII:TZ47U31L0P)	DEXTROAMPHETAMINE SULFATE	1.25 mg
DEXTROAMPHETAMINE SACCHARATE (UNII: GE34ST47ST) (DEXTROAMPHETAMINE - UNII:TZ47U31L0P)	DEXTROAMPHETAMINE SACCHARATE	1.25 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)	
FD&C BLUE NO. 1 (UNII: H88K7436TO)	
MAGNESIUM STEARATE (UNII: 70097M6I8K)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
SUCROSE (UNII: C151H8M554)	

Product Characteristics

Color	BLUE	**Score**	4 pieces
Shape	OVAL	**Size**	8mm
Flavor		**Imprint Code**	9;952
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68382-950-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/31/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207340	10/31/2017	

DEXTROAMPHETAMINE SACCHARATE, AMPHETAMINE ASPARTATE, DEXTROAMPHETAMINE SULFATE AND AMPHETAMINE SULFATE

dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:68382-951
Route of Administration	ORAL	**DEA Schedule**	CII

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AMPHETAMINE SULFATE (UNII: 6DPSN7K6AR) (AMPHETAMINE - UNII:DE08037KNI)	AMPHETAMINE SULFATE	1.875 mg
AMPHETAMINE ASPARTATE MONOHYDRATE (UNII: O42PWL3O1A) (AMPHETAMINE - UNII:CK6CO1Q1Z7)	AMPHETAMINE ASPARTATE MONOHYDRATE	1.875 mg
DEXTROAMPHETAMINE SULFATE (UNII: 1TS9I1G57N) (DEXTROAMPHETAMINE - UNII:TZ47U31L0P)	DEXTROAMPHETAMINE SULFATE	1.875 mg
DEXTROAMPHETAMINE SACCHARATE (UNII: GE34ST47ST) (DEXTROAMPHETAMINE - UNII:TZ47U31L0P)	DEXTROAMPHETAMINE SACCHARATE	1.875 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)	
FD&C BLUE NO. 1 (UNII: H88K7436TO)	
MAGNESIUM STEARATE (UNII: 70097M6I8K)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
SUCROSE (UNII: C151H8M554)	

Product Characteristics

Color	BLUE	**Score**	4 pieces
Shape	ROUND	**Size**	8mm
Flavor		**Imprint Code**	9;953
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68382-951-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/31/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207340	10/31/2017	

DEXTROAMPHETAMINE SACCHARATE, AMPHETAMINE ASPARTATE, DEXTROAMPHETAMINE SULFATE AND AMPHETAMINE SULFATE

dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:68382-952
Route of Administration	ORAL	**DEA Schedule**	CII

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AMPHETAMINE SULFATE (UNII: 6DPSN7K6AR) (AMPHETAMINE - UNII:DE08037KNI)	AMPHETAMINE SULFATE	2.5 mg
AMPHETAMINE ASPARTATE MONOHYDRATE (UNII: O42PWL3O1A) (AMPHETAMINE - UNII:CK6CO1Q1Z7)	AMPHETAMINE ASPARTATE MONOHYDRATE	2.5 mg
DEXTROAMPHETAMINE SULFATE (UNII: 1TS9I1G57N) (DEXTROAMPHETAMINE - UNII:TZ47U31L0P)	DEXTROAMPHETAMINE SULFATE	2.5 mg
DEXTROAMPHETAMINE SACCHARATE (UNII: GE34ST47ST) (DEXTROAMPHETAMINE - UNII:TZ47U31L0P)	DEXTROAMPHETAMINE SACCHARATE	2.5 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)	
FD&C BLUE NO. 1 (UNII: H88K7436TO)	
MAGNESIUM STEARATE (UNII: 70097M6I8K)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
SUCROSE (UNII: C151H8M554)	

Product Characteristics

Color	BLUE	**Score**	4 pieces
Shape	OVAL	**Size**	10mm
Flavor		**Imprint Code**	9;952
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68382-952-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/31/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207340	10/31/2017	

DEXTROAMPHETAMINE SACCHARATE, AMPHETAMINE ASPARTATE, DEXTROAMPHETAMINE SULFATE AND AMPHETAMINE SULFATE

dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:68382-953
Route of Administration	ORAL	**DEA Schedule**	CII

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AMPHETAMINE SULFATE (UNII: 6DPSN7K6AR) (AMPHETAMINE - UNII:DE08037KNI)	AMPHETAMINE SULFATE	3.125 mg
AMPHETAMINE ASPARTATE MONOHYDRATE (UNII: O42PWL3O1A) (AMPHETAMINE - UNII:CK6CO1Q1Z7)	AMPHETAMINE ASPARTATE MONOHYDRATE	3.125 mg
DEXTROAMPHETAMINE SULFATE (UNII: 1TS9I1G57N) (DEXTROAMPHETAMINE - UNII:TZ47U31L0P)	DEXTROAMPHETAMINE SULFATE	3.125 mg
DEXTROAMPHETAMINE SACCHARATE (UNII: GE34ST47ST) (DEXTROAMPHETAMINE - UNII:TZ47U31L0P)	DEXTROAMPHETAMINE SACCHARATE	3.125 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I8K)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
SUCROSE (UNII: C151H8M554)	

Product Characteristics

Color	ORANGE (peach)	**Score**	4 pieces
Shape	OVAL	**Size**	8mm
Flavor		**Imprint Code**	9;953
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68382-953-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/31/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207340	10/31/2017	

DEXTROAMPHETAMINE SACCHARATE, AMPHETAMINE ASPARTATE, DEXTROAMPHETAMINE SULFATE AND AMPHETAMINE SULFATE

dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:68382-954
Route of Administration	ORAL	**DEA Schedule**	CII

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AMPHETAMINE SULFATE (UNII: 6DPSN7K6AR) (AMPHETAMINE - UNII:DE08037KNI)	AMPHETAMINE SULFATE	3.75 mg
AMPHETAMINE ASPARTATE MONOHYDRATE (UNII: O42PWL3O1A) (AMPHETAMINE - UNII:CK6CO1Q1Z7)	AMPHETAMINE ASPARTATE MONOHYDRATE	3.75 mg
DEXTROAMPHETAMINE SULFATE (UNII: 1TS9I1G57N) (DEXTROAMPHETAMINE - UNII:TZ47U31L0P)	DEXTROAMPHETAMINE SULFATE	3.75 mg
DEXTROAMPHETAMINE SACCHARATE (UNII: GE34ST47ST) (DEXTROAMPHETAMINE - UNII:TZ47U31L0P)	DEXTROAMPHETAMINE SACCHARATE	3.75 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I8K)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
SUCROSE (UNII: C151H8M554)	

Product Characteristics

Color	ORANGE (peach)	**Score**	4 pieces
Shape	ROUND	**Size**	8mm
Flavor		**Imprint Code**	9;954
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68382-954-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/31/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207340	10/31/2017	

DEXTROAMPHETAMINE SACCHARATE, AMPHETAMINE ASPARTATE, DEXTROAMPHETAMINE SULFATE AND AMPHETAMINE SULFATE

dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:68382-955
Route of Administration	ORAL	**DEA Schedule**	CII

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AMPHETAMINE SULFATE (UNII: 6DPSN7K6AR) (AMPHETAMINE - UNII:DE08037KNI)	AMPHETAMINE SULFATE	5 mg
AMPHETAMINE ASPARTATE MONOHYDRATE (UNII: O42PWL3O1A) (AMPHETAMINE - UNII:CK6CO1Q1Z7)	AMPHETAMINE ASPARTATE MONOHYDRATE	5 mg
DEXTROAMPHETAMINE SULFATE (UNII: 1TS9I1G57N) (DEXTROAMPHETAMINE - UNII:TZ47U31L0P)	DEXTROAMPHETAMINE SULFATE	5 mg
DEXTROAMPHETAMINE SACCHARATE (UNII: GE34ST47ST) (DEXTROAMPHETAMINE - UNII:TZ47U31L0P)	DEXTROAMPHETAMINE SACCHARATE	5 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CV7WJK4QI)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
SUCROSE (UNII: C151H8M554)	

Product Characteristics

Color	ORANGE (peach)	**Score**	4 pieces
Shape	OVAL	**Size**	15mm
Flavor		**Imprint Code**	5(93)
Contains:			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68382-935-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	06/16/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207540	06/16/2017	

DEXTROAMPHETAMINE SACCHARATE, AMPHETAMINE ASPARTATE, DEXTROAMPHETAMINE SULFATE AND AMPHETAMINE SULFATE

dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:68382-936
Route of Administration	ORAL	**DEA Schedule**	CII

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AMPHETAMINE SULFATE (UNII: 63PSV9X4G8) (AMPHETAMINE - UNII:CK7RUCE7ZN)	AMPHETAMINE SULFATE	7.5 mg
AMPHETAMINE ASPARTATE MONOHYDRATE (UNII: O42PVL2O14) (AMPHETAMINE - UNII:CK7RUCE7ZN)	AMPHETAMINE ASPARTATE MONOHYDRATE	7.5 mg
DEXTRO AMPHETAMINE SULFATE (UNII: 1578OS5270) (DEXTRO AMPHETAMINE - UNII:7W1T3Z7S1F)	DEXTRO AMPHETAMINE SULFATE	7.5 mg
DEXTRO AMPHETAMINE SACCHARATE (UNII: GT4A5YS67T) (DEXTRO AMPHETAMINE - UNII:7Z7U5 1F)	DEXTRO AMPHETAMINE SACCHARATE	7.5 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CV7WJK4QI)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
SUCROSE (UNII: C151H8M554)	

Product Characteristics

Color	ORANGE (peach)	**Score**	4 pieces
Shape	OVAL	**Size**	15mm
Flavor		**Imprint Code**	5(936)
Contains:			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68382-936-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	06/16/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207540	06/16/2017	

Labeler - Zydus Pharmaceuticals (USA) Inc. (116860186)

Registrant - Strider Pharmaceuticals (USA) LLC (969928351)

Establishment

Name	Address	ID/FEI	Business Operations
Strider Pharmaceuticals (USA) LLC		969928351	ANALYSIS(68382-936, 68382-935), LABELING(68382-935), LABELING(68382-936), PACKAGING(68382-935, 68382-936), MANUFACTURE(68382-936, 68382-935), API MANUFACTURE(68382-935, 68382-936), STERILE PRODUCT(68382-936, 68382-935)