

DEXTROAMPHETAMINE SACCHARATE, AMPHETAMINE ASPARTATE MONOHYDRATE, DEXTROAMPHETAMINE SULFATE AND AMPHETAMINE SULFATE- dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate tablet
Sandoz Inc

Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate and Amphetamine Sulfate Tablets (Mixed Salts of a Single Entity Amphetamine Product)

Rx Only

WARNING: ABUSE, MISUSE, AND ADDICTION

Dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate has a high potential for abuse and misuse, which can lead to the development of a substance use disorder, including addiction. Misuse and abuse of CNS stimulants, including dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate, can result in overdose and death (see OVERDOSAGE), and this risk is increased with higher doses or unapproved methods of administration, such as snorting or injection.

Before prescribing dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate, assess each patient's risk for abuse, misuse, and addiction. Educate patients and their families about these risks, proper storage of the drug, and proper disposal of any unused drug. Throughout dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate treatment, reassess each patient's risk of abuse, misuse, and addiction and frequently monitor for signs and symptoms of abuse, misuse, and addiction (see WARNINGS and DRUG ABUSE AND DEPENDENCE).

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	10 mg	20 mg	30 mg
Dextroamphetamine Saccharate	1.25 mg	2.5 mg	5 mg	7.5 mg
Amphetamine Aspartate Monohydrate	1.25 mg	2.5 mg	5 mg	7.5 mg
Dextroamphetamine	1.25 mg	2.5 mg	5 mg	7.5 mg

Sulfate, USP				
Amphetamine Sulfate, USP	1.25 mg	2.5 mg	5 mg	7.5 mg
Total Amphetamine Base Equivalence	3.13 mg	6.3 mg	12.6 mg	18.8 mg

Inactive Ingredients: lactose monohydrate, pregelatinized starch (corn) and magnesium stearate.

Color Additives: FD&C blue No. 1 aluminum lake (for 5 mg and 10 mg strengths) and FD&C yellow No. 6 aluminum lake (for 20 mg and 30 mg strengths).

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

Mixed salts of a single entity amphetamine product contain d-amphetamine and l-amphetamine salts in the ratio of 3:1. Following administration of a single dose 10 mg or 30 mg of mixed salts of a single entity amphetamine product 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 (9.77 to 11 hours vs. 11.5 to 13.8 hours). The PK parameters (C_{max} , 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 mixed salts of a single entity amphetamine product has not been studied.

Metabolism and Excretion

Amphetamine is reported to be oxidized at the 4 position of the benzene ring to form 4-hydroxyamphetamine, or on the side chain α or β carbons to form alpha-hydroxy-amphetamine or norephedrine, respectively. Norephedrine and 4-hydroxy-amphetamine are both active and each is subsequently oxidized to form 4-hydroxy-norephedrine. Alpha-hydroxy-amphetamine undergoes deamination to form 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 auto-inhibition and the lack of information on the concentration of these metabolites relative to *in vivo* concentrations, no predilections 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 (Mixed salts of a single entity amphetamine product) is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) and Narcolepsy.

Attention Deficit Hyperactivity Disorder (ADHD)

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

CONTRAINDICATIONS

In patients known to be hypersensitive to amphetamine, or other components of mixed salts of a single entity amphetamine product. 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

Abuse, Misuse, and Addiction

Dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate has a high potential for abuse and misuse. The use of dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate exposes individuals to the risks of abuse and misuse, which can lead to the development of a substance use disorder, including addiction.

Dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate can be diverted for non-medical use into illicit channels or distribution (see DRUG ABUSE and DEPENDENCE: Abuse). Misuse and abuse of CNS stimulants, including dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate, can result in overdose and death (see OVERDOSAGE), and this risk is increased with higher doses or unapproved methods of administration, such as snorting or injection.

Before prescribing dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate, assess each patient's risk for abuse, misuse, and addiction. Educate patients and their families about these risks and proper disposal of any unused drug. Advise patients to store amphetamine sulfate in a safe place, preferably locked, and instruct patients to not give dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate to anyone else. Throughout dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate treatment, reassess each patient's risk of abuse, misuse, and addiction and frequently monitor for signs and symptoms of abuse, misuse, and addiction.

Risks to Patients with Serious Cardiac Disease

Sudden death has been reported in patients with structural cardiac abnormalities or other serious cardiac disease who were treated with CNS stimulant treatment at the recommended ADHD dosages.

Avoid dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate use in patients with known structural cardiac abnormalities, cardiomyopathy, serious cardiac arrhythmia, coronary artery disease, or other serious cardiac disease.

Increased Blood Pressure and Heart Rate

CNS stimulants cause an increase in blood pressure (mean increase about 2 to 4 mm Hg) and heart rate (mean increase about 3 to 6 bpm). Some patients may have larger

increases. Monitor all dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate-treated patients for potential tachycardia and hypertension.

Psychiatric Adverse Reactions

Exacerbation of Preexisting Psychosis

CNS stimulants may exacerbate symptoms of behavior disturbance and thought disorder in patients with a pre-existing psychotic disorder.

Induction of a Manic Episode in Patients with Bipolar Disorder

CNS stimulants may induce a manic or mixed episode in patients. Prior to initiating treatment, screen patients for risk factors for developing a manic episode (e.g., comorbid or history of depressive symptoms or a family history of suicide, bipolar disorder, or depression).

New Psychotic or Manic Symptoms

CNS stimulants, at recommended doses, may cause psychotic or manic symptoms (e.g., hallucinations, delusional thinking, or mania) in patients without a prior history of psychotic illness or mania. In a pooled analysis of multiple short-term, placebo-controlled studies of CNS stimulants, psychotic or manic symptoms occurred in approximately 0.1% of CNS stimulant-treated patients, compared with 0% of placebo-treated patients. If such symptoms occur, consider discontinuing dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate.

Long-Term Suppression of Growth in Pediatric Patients

CNS stimulants have been associated with weight loss and slowing of growth rate in pediatric patients. Closely monitor growth (weight and height) in dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate-treated pediatric patients treated with CNS stimulants.

Pediatric patients who are not growing or gaining weight as expected may need to have their treatment interrupted (see PRECAUTIONS, PEDIATRIC USE).

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, used to treat ADHD are associated with peripheral vasculopathy, including Raynaud's phenomenon. Signs and symptoms are usually intermittent and mild; however, sequelae include digital ulceration and/or soft tissue breakdown. Effects of peripheral vasculopathy, including Raynaud's phenomenon, were observed in postmarketing reports and at the therapeutic dosage of

CNS stimulants in all age groups throughout the course of treatment. Signs and symptoms generally improved after dosage reduction or discontinuation of the CNS stimulant. Careful observation for digital changes is necessary during dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate treatment. Further clinical evaluation (e.g., rheumatology referral) may be appropriate for dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate-treated patients who develop signs or symptoms of peripheral vasculopathy.

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 systems 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). The co-administration with cytochrome P450 (CYP2D6) inhibitors increase the risk with increased exposure to dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate, amphetamine sulfate. In these situations, consider an alternative non-serotonergic drug 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, amphetamine sulfate with MAOI drugs is contraindicated (see CONTRAINDICATIONS).

Discontinue treatment with dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate, amphetamine sulfate 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, amphetamine sulfate with other serotonergic drugs or CYP2D6 inhibitors is clinically warranted, initiate dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate, amphetamine sulfate 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.

Motor and Verbal Tics, and Worsening of Tourette's Syndrome

CNS stimulants, including amphetamine sulfate, have been associated with the onset or exacerbation of motor and verbal tics. Worsening of Tourette's syndrome has also been reported. Before initiating dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate assess the family history and clinically evaluate patients for tics or Tourette's syndrome. Regularly monitor patients for the emergence or worsening of tics or Tourette's syndrome with dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine

sulfate, and discontinue treatment if clinically appropriate.

PRECAUTIONS

Information for Patients

Advise the patient to read the FDA-approved patient labeling (Medication Guide).

Abuse, Misuse, and Addiction

Educate patients and their families about the risks of abuse, misuse, and addiction of dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate, which can lead to overdose and death, and proper disposal of any unused drug (see WARNINGS, DRUG ABUSE AND DEPENDENCE, OVERDOSAGE). Advise patients to store dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate in a safe place, preferably locked, and instruct patients to not give dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate to anyone else.

Risks to Patients with Serious Cardiac Disease

Advise patients that there are potential risks to patients with serious cardiac disease, including sudden death, with dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate use. Instruct patients to contact a healthcare provider immediately if they develop symptoms such as exertional chest pain, unexplained syncope, or other symptoms suggestive of cardiac disease (see WARNINGS).

Increased Blood Pressure and Heart Rate

Advise patients that dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate can elevate blood pressure and heart rate (see WARNINGS).

Psychiatric Adverse Reactions

Advise patients that dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate, at recommended doses, can cause psychotic or manic symptoms, even in patients without prior history of psychotic symptoms or mania (see WARNINGS).

Long-Term Suppression of Growth in Pediatric Patients

Advise patients that dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate may cause slowing of growth including weight loss (see WARNINGS).

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

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.**
- Further clinical evaluation (e.g., rheumatology referral) may be appropriate for certain patients.

Serotonin Syndrome

Caution patients about the risk of serotonin syndrome with concomitant use of dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate and other serotonergic drugs including SSRIs, SNRIs, triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, tryptophan, buspirone, St. John's Wort, and with drugs that impair metabolism of serotonin (in particular MAOIs, both those intended to treat psychiatric disorders and also others such as linezolid (see CONTRAINDICATIONS, WARNINGS, and DRUG INTERACTIONS)). Advise patients to contact their healthcare provider or report to the emergency room if they experience signs or symptoms of serotonin syndrome.

Motor and Verbal Tics, and Worsening of Tourette's Syndrome

Advise patients that motor and verbal tics and worsening of Tourette's Syndrome may occur during treatment with dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate. Instruct the patients to notify their healthcare provider if emergence or worsening of tics or Tourette's syndrome occurs (see WARNINGS).

Drug Interactions

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, amphetamine sulfate concomitantly or within 14 days after discontinuing MAOI (see CONTRAINDICATIONS and WARNINGS).

Serotonergic Drugs

The concomitant use of dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate, amphetamine sulfate 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, amphetamine sulfate initiation or dosage increase. If serotonin syndrome occurs, discontinue dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate, amphetamine sulfate and the concomitant serotonergic drug(s) (see WARNINGS and PRECAUTIONS).

CYP2D6 Inhibitors

The concomitant use of dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate, amphetamine sulfate and CYP2D6 inhibitors may increase the exposure of dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate, amphetamine sulfate 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, amphetamine sulfate initiation and after a dosage increase. If serotonin syndrome occurs, discontinue dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate, amphetamine sulfate and the CYP2D6 inhibitor (see WARNINGS, OVERDOSAGE).

Acidifying Agents

Lower blood levels and efficacy of amphetamines. Increase dose based on clinical response. Examples of acidifying agents include gastrointestinal acidifying agents and urinary acidifying agents.

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 and gastrointestinal alkalinizing agents should be avoided. Examples of alkalinizing agents include gastrointestinal alkalinizing agents and urinary alkalinizing agents.

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.

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 (T_{max}) 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 d, l-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

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 mixed salts of a single entity amphetamine product (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 mixed salts of a single entity amphetamine product (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

Amphetamine, in the enantiomer ratio present in mixed salts of a single entity amphetamine product (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 mg/kg/day 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 to pregnant animals. Administration of these doses was also associated with severe maternal toxicity.

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

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

Mixed salts of a single entity amphetamine product have not been studied in the geriatric population.

ADVERSE REACTIONS

Cardiovascular

Palpitations, 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, motor and verbal tics, aggression, anger, logorrhea, dermatillomania.

Eye Disorders

Vision blurred, mydriasis.

Gastrointestinal

Dryness of the mouth, unpleasant taste, diarrhea, constipation, intestinal ischemia and 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.

To report SUSPECTED ADVERSE REACTIONS, contact Sandoz Inc. at 1-800-

525-8747 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG ABUSE AND DEPENDENCE

Controlled Substance

Mixed salts of a single entity amphetamine product contains amphetamine, a Schedule II controlled substance.

Abuse

Dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate has a high potential for abuse and misuse which can lead to the development of a substance use disorder, including addiction (see WARNINGS and PRECAUTIONS). Dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate can be diverted for non-medical use into illicit channels or distribution.

Abuse is the intentional non-therapeutic use of a drug, even once, to achieve a desired psychological or physiological effect. Misuse is the intentional use, for therapeutic purposes, of a drug by an individual in a way other than prescribed by a health care provider or for whom it was not prescribed. Drug addiction is a cluster of behavioral, cognitive, and physiological phenomena that may include a strong desire to take the drug, difficulties in controlling drug use (e.g., continuing drug use despite harmful consequences, giving a higher priority to drug use than other activities and obligations), and possible tolerance or physical dependence.

Misuse and abuse of amphetamines may cause increased heart rate, respiratory rate, or blood pressure; sweating; dilated pupils; hyperactivity; restlessness; insomnia; decreased appetite; loss of coordination; tremors; flushed skin; vomiting; and/or abdominal pain. Anxiety, psychosis, hostility, aggression, and suicidal or homicidal ideation have also been observed with CNS stimulants abuse and/or misuse. Misuse and abuse of CNS stimulants, including dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate, can result in overdose and death (see OVERDOSAGE), and this risk is increased with higher doses or unapproved methods of administration, such as snorting or injection.

Dependence

Physical Dependence

Dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate may produce physical dependence. Physical dependence is a state that develops as a result of physiological adaptation in response to repeated drug use, manifested by withdrawal signs and symptoms after abrupt discontinuation or a significant dose reduction of a drug.

Withdrawal signs and symptoms after abrupt discontinuation or dose reduction following prolonged use of CNS stimulants including dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate include dysphoric mood; depression; fatigue; vivid, unpleasant dreams; insomnia or hypersomnia; increased appetite; and psychomotor retardation or agitation.

Tolerance

Dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate may produce tolerance. Tolerance is a physiological state characterized by a reduced response to a drug after repeated administration (i.e., a higher dose of a drug is required to produce the same effect that was once obtained at a lower dose).

OVERDOSAGE

Clinical Effects of Overdose

Overdose of CNS stimulants is characterized by the following sympathomimetic effects:

- Cardiovascular effects including tachyarrhythmias, and hypertension or hypotension. Vasospasm, myocardial infarction, or aortic dissection may precipitate sudden cardiac death. Takotsubo cardiomyopathy may develop.
- CNS effects including psychomotor agitation, confusion, and hallucinations. Serotonin syndrome, seizures, cerebral vascular accidents, and coma may occur.
- Life-threatening hyperthermia (temperatures greater than 104°F) and rhabdomyolysis may develop.

Overdose Management

Consider the possibility of multiple drug ingestion. D-amphetamine is not dialyzable. Consider contacting the Poison Help line (1-800-222-1222) or a medical toxicologist for additional overdose management recommendations.

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.

Prior to treating patients with dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate assess:

- for the presence of cardiac disease (i.e., perform a careful history, family history of sudden death or ventricular arrhythmia, and physical exam) (see WARNINGS).

- the family history and clinically evaluate patients for motor or verbal tics or Tourette's syndrome before initiating dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate (see WARNINGS).

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 (Mixed salts of a single entity amphetamine product), for oral administration, are available as:

5 mg

Dark blue, round, biconvex tablets, debossed "E" over "84" on one side and double-bisected on the other side and supplied as:

NDC 0185-2098-01 bottles of 100

10 mg

Dark blue, round, biconvex tablets, debossed "E" over "111" on one side and double-bisected on the other side and supplied as:

NDC 0185-0842-01 bottles of 100

20 mg

Dark orange, round, biconvex tablets, debossed "E" over "401" on one side and double-bisected on the other side and supplied as:

NDC 0185-0853-01 bottles of 100

30 mg

Dark orange, round, biconvex tablets, debossed "E" over "404" on one side and double-bisected on the other side and supplied as:

NDC 0185-2099-01 bottles of 100

Dispense contents in a tight, light-resistant container as defined in the USP with a child-resistant closure, as required. Protect from light and moisture. Keep tightly closed.

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

KEEP OUT OF THE REACH OF CHILDREN.

Distributed by

Sandoz Inc., Princeton, NJ 08540

1325A00

Revised: 04/2024

Medication Guide

Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate and Amphetamine Sulfate Tablets, CII (dex-troe-am-FET-ah-meen)

What is the most important information I should know about mixed salts of a single entity amphetamine product?

Mixed salts of a single entity amphetamine product may cause serious side effects, including:

- **Abuse, misuse, and addiction.** Mixed salts of a single entity amphetamine product has a high chance for abuse and misuse and may lead to substance use problems, including addiction. Misuse and abuse of mixed salts of a single entity amphetamine product, other amphetamine containing medicines, and methylphenidate containing medicines, can lead to overdose and death. The risk of overdose and death is increased with higher doses of mixed salts of a single entity amphetamine product or when it is used in ways that are not approved, such as snorting or injection.
- o Your healthcare provider should check you or your child's risk for abuse, misuse, and addiction before starting treatment with mixed salts of a single entity amphetamine product and will monitor you or your child during treatment.
- o Mixed salts of a single entity amphetamine product may lead to physical dependence after prolonged use, even if taken as directed by your healthcare provider.
- o Do not give mixed salts of a single entity amphetamine product to anyone else. See **"What is mixed salts of a single entity amphetamine product?"** for more information.
- o Keep mixed salts of a single entity amphetamine product in a safe place and properly dispose of any unused medicine. See **"How should I store mixed salts of a single entity amphetamine product?"** for more information.
- o Tell your healthcare provider if you or your child have

ever abused or been dependent on alcohol, prescription medicines, or street drugs.

- o **Risks for people with serious heart disease:**
Sudden death has happened in people who have heart defects or other serious heart disease.

Your healthcare provider should check you or your child carefully for heart problems before starting treatment with mixed salts of a single entity amphetamine product. Tell your healthcare provider if you or your child have any heart problems, heart disease, or heart defects.

Call your healthcare provider right away or go to the nearest hospital emergency room right away if you or your child have any signs of heart problems such as chest pain, shortness of breath, or fainting during treatment with mixed salts of a single entity amphetamine product.

- **Increased blood pressure and heart rate.**
Your healthcare provider should check you or your child's blood pressure and heart rate regularly during treatment with mixed salts of a single entity amphetamine product.
- **Mental (psychiatric) problems, including:**
 - o new or worse behavior and thought problems
 - o new or worse bipolar illness
 - o new psychotic symptoms (such as hearing voices, or seeing or believing things that are not real) or new manic symptoms

Tell your healthcare provider about any mental problems you or your child have, or about a family history of suicide, bipolar illness, or depression.

Call your healthcare provider right away if you or your child have any new or worsening mental symptoms or problems during treatment with mixed salts of a single entity amphetamine product, especially hearing voices, seeing or believing things that are not real, or new manic symptoms.

What is mixed salts of a single entity amphetamine product?

Mixed salts of a single entity amphetamine product is a central nervous system (CNS) stimulant prescription medicine used for the treatment of:

- Attention-Deficit Hyperactivity Disorder (ADHD) in children 3 to 17 years of age. Mixed salts of a single entity amphetamine product may help increase attention and decrease impulsiveness and hyperactivity in people with ADHD.
- a sleep disorder called narcolepsy in people 6 years

and older. It is not known if mixed salts of a single entity amphetamine product is safe and effective in children with ADHD under 3 years of age. It is not known if mixed salts of a single entity amphetamine product is safe and effective in children with Narcolepsy under 6 years of age.

Mixed salts of a single entity amphetamine product is a federally controlled substance (CII) because it contains amphetamine that can be a target for people who abuse prescription medicines or street drugs. Keep mixed salts of a single entity amphetamine product in a safe place to protect it from theft. Never give your mixed salts of a single entity amphetamine product to anyone else because it may cause death or harm them. Selling or giving away mixed salts of a single entity amphetamine product may harm others and is against the law.

Do not take mixed salts of a single entity amphetamine product if you or your child:

- are allergic to amphetamine products or any of the ingredients in mixed salts of a single entity amphetamine product. See the end of this Medication Guide for a complete list of ingredients in mixed salts of a single entity amphetamine product.
- are taking or have taken within the past 14 days, a medicine used to treat depression called a monoamine oxidase inhibitor (MAOI) including the antibiotic linezolid or the intravenous medicine methylene blue.

Before taking mixed salts of a single entity amphetamine product, tell your healthcare provider about all of your or your child's medical conditions, including if you or your child:

- have heart problems, heart disease, heart defects, or high blood pressure
- have mental problems including psychosis, mania, bipolar illness, or depression, or have a family history of suicide, bipolar illness, or depression
- have kidney problems
- have seizures or have had an abnormal brain wave test (EEG)
- have circulation problems in fingers or toes
- have or had repeated movements or sounds (tics) or Tourette's syndrome, or have a family history of tics or Tourette's syndrome.
- are pregnant or plan to become pregnant. It is not known if mixed salts of a single entity amphetamine

product will harm the unborn baby. Tell your healthcare provider if you or your child become pregnant during treatment with mixed salts of a single entity amphetamine product.

- are breastfeeding or plan to breastfeed. Mixed salts of a single entity amphetamine product passes into breast milk. You or your child should not breastfeed during treatment with mixed salts of a single entity amphetamine product. Talk to your healthcare provider about the best way to feed the baby during treatment with mixed salts of a single entity amphetamine product.

Tell your healthcare provider about all of the medicines that you or your child take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Mixed salts of a single entity amphetamine product and some medicines may interact with each other and cause serious side effects. Sometimes the doses of other medicines will need to be changed during treatment with mixed salts of a single entity amphetamine product. Your healthcare provider will decide if mixed salts of a single entity amphetamine product can be taken with other medicines.

Especially tell your healthcare provider if you or your child take:

- selective serotonin reuptake inhibitors (SSRIs)
- medicines used to treat migraine headaches called triptans
- lithium
- tramadol
- buspirone
- serotonin norepinephrine reuptake inhibitors (SNRIs)
- tricyclic antidepressants
- fentanyl
- tryptophan
- St. John's Wort

Know the medicines that you or your child take. Keep a list of your or your child's medicines with you to show your healthcare provider and pharmacist when you or your child get a new medicine.

Do not start any new medicine during treatment with mixed salts of a single entity amphetamine product without talking to your healthcare provider first.

How should mixed salts of a single entity amphetamine product be taken?

- Take mixed salts of a single entity amphetamine product exactly as prescribed by your or your child's healthcare provider.
- Your healthcare provider may change the dose if needed.
- The first dose of the day is usually taken when you first wake up.
- Mixed salts of a single entity amphetamine product can be taken with or without food.

If you or your child take too much mixed salts of a single entity amphetamine product, call your healthcare provider or Poison Help line at 1-800-222-1222 or go to the nearest hospital emergency room right away.

What are possible side effects of mixed salts of a single entity amphetamine product?

Mixed salts of a single entity amphetamine product may cause serious side effects, including:

See **"What is the most important information I should know about mixed salts of a single entity amphetamine product?"**

- **Slowing of growth (height and weight) in children.** Children should have their height and weight checked often during treatment with mixed salts of a single entity amphetamine product. Your healthcare provider may stop your child's mixed salts of a single entity amphetamine product treatment if they are not growing or gaining weight as expected.
- **Seizures.** Your healthcare provider may stop treatment with mixed salts of a single entity amphetamine product if you or your child have a seizure.
- **Circulation problems in fingers and toes (peripheral vasculopathy, including Raynaud's phenomenon). Signs and symptoms may include:**
 - o fingers or toes may feel numb, cool, painful
 - o fingers or toes may change color from pale, to blue, to red

Tell your healthcare provider if you have or your child has any numbness, pain, skin color change, or sensitivity to temperature in your fingers or toes.

Call your healthcare provider right away if you have or your child have any signs of unexplained wounds appearing on fingers or toes during treatment with mixed salts of a single entity amphetamine product.

- Serotonin syndrome. This problem may happen when

mixed salts of a single entity amphetamine product is taken with certain other medicines and may be life-threatening. Stop taking mixed salts of a single entity amphetamine product and call your healthcare provider or go to the nearest hospital emergency room right away if you or your child develop any of the following signs and symptoms of serotonin syndrome:

- agitation, hallucinations, coma
- fast heartbeat
- flushing
- seizures
- loss of coordination
- confusion
- dizziness
- changes in blood pressure
- sweating or fever
- nausea, vomiting, or diarrhea
- muscle stiffness or tightness
- high body temperature (hyperthermia)
- **New or worsening tics or worsening Tourette's syndrome.** Tell your healthcare provider if you or your child get any new or worsening tics or worsening Tourette's syndrome during treatment with mixed salts of a single entity amphetamine product.

The most common side effects of mixed salts of a single entity amphetamine product include:

- stomachache
- decreased appetite
- nervousness

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

These are not all the possible side effects of mixed salts of a single entity amphetamine product.

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 mixed salts of a single entity amphetamine product?

- Store mixed salts of a single entity amphetamine product at room temperature between 68°F to 77°F (20°C to 25°C).
- Protect mixed salts of a single entity amphetamine product from light.
- Store mixed salts of a single entity amphetamine product in a safe place, like a locked cabinet.
- Dispose of remaining, unused, or expired mixed salts of a single entity amphetamine product by a medicine

take-back program at a U.S. Drug Enforcement Administration (DEA) authorized collection site. If no take-back program or DEA authorized collector is available, mix the mixed salts of a single entity amphetamine product with an undesirable, nontoxic substance such as dirt, cat litter, or used coffee grounds to make it less appealing to children and pets. Place the mixture in a container such as a sealed plastic bag and throw away mixed salts of a single entity amphetamine product in the household trash. Visit www.fda.gov/drugdisposal for additional information on disposal of unused medicines.

Keep mixed salts of a single entity amphetamine product and all medicines out of the reach of children.

General information about the safe and effective use of mixed salts of a single entity amphetamine product

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use mixed salts of a single entity amphetamine product for a condition for which it was not prescribed. Do not give mixed salts of a single entity amphetamine product to other people, even if they have the same condition. It may harm them and it is against the law. You can ask your healthcare provider or pharmacist for information about mixed salts of a single entity amphetamine product that was written for healthcare professionals.

What are the ingredients in mixed salts of a single entity amphetamine product?

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

Inactive Ingredients: lactose monohydrate, pregelatinized starch (corn) and magnesium stearate.

Color Additives: FD&C blue No. 1 aluminum lake (for 5 mg and 10 mg strengths) and FD&C yellow No. 6 aluminum lake (for 20 mg and 30 mg strengths).

For additional medication guide please go to www.us.sandoz.com or call 1-800-525-8747.

Distributed by
Sandoz Inc., Princeton, NJ 08540
1325A00

This Medication Guide has been approved by the U.S. Food and Drug Administration.
Revised: 04/2024

Mixed Salts of a Single Entity Amphetamine Product 5 mg x 100 Tablets -

Label

NDC 0185-0831-01

**Dextroamphetamine Saccharate,
Amphetamine Aspartate,
Dextroamphetamine Sulfate and
Amphetamine Sulfate Tablets**

(Mixed Salts of A Single Entity Amphetamine Product)

5 mg

PHARMACIST: Please dispense with
Medication Guide provided separately.

Rx Only

100 Tablets

Sandoz

NDC 0185-0831-01

**Dextroamphetamine Saccharate,
Amphetamine Aspartate,
Dextroamphetamine Sulfate and
Amphetamine Sulfate Tablets**

(Mixed Salts of A Single Entity
Amphetamine Product)

5 mg

PHARMACIST: Please dispense with
Medication Guide provided separately.

Rx Only

100 Tablets

SANDOZ

Each tablet contains: Dextroamphetamine saccharate 1.25 mg, amphetamine aspartate monohydrate 1.25 mg, dextroamphetamine sulfate, USP 1.25 mg and amphetamine sulfate, USP 1.25 mg. (Total amphetamine base equivalent 3.13 mg)

USUAL ADULT DOSAGE: One tablet once or twice daily. See accompanying literature for complete prescribing information. Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Dispense contents in a tight, light-resistant container as defined in the USP with a child-resistant closure, as required. Protect from light and moisture. **KEEP TIGHTLY CLOSED.**

KEEP OUT OF THE REACH OF CHILDREN.

Manufactured by Sandoz Inc.
Princeton, NJ 08540

46192674

Rev. 05/2017

0185-0831-01

Mixed Salts of a Single Entity Amphetamine Product 5 mg x 100 Tablets - Label

NDC 0185-2098-01

**Dextroamphetamine Saccharate,
Amphetamine Aspartate,
Dextroamphetamine Sulfate and
Amphetamine Sulfate Tablets**

(Mixed Salts of A Single Entity
Amphetamine Product)

5 mg

PHARMACIST: Please dispense with
Medication Guide provided separately.

Rx Only

100 Tablets

Sandoz

NDC 0185-2098-01
**Dextroamphetamine Saccharate,
Amphetamine Aspartate,
Dextroamphetamine Sulfate and
Amphetamine Sulfate Tablets**
(Mixed Salts of A Single Entity
Amphetamine Product)

5 mg

PHARMACIST: Please dispense with
Medication Guide provided separately.
Rx Only
100 Tablets
SANDOZ

Each tablet contains: Dextroamphetamine saccharate 1.25 mg, amphetamine aspartate monohydrate 1.25 mg, dextroamphetamine sulfate, USP 1.25 mg and amphetamine sulfate, USP 1.25 mg. (Total amphetamine base equivalent 3.13 mg)
USUAL ADULT DOSAGE: One tablet once or twice daily. See accompanying literature for complete prescribing information.
Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].
Dispense contents in a tight, light-resistant container as defined in the USP with a child-resistant closure, as required. Protect from light and moisture. **KEEP TIGHTLY CLOSED. KEEP OUT OF THE REACH OF CHILDREN.**
Distributed by Sandoz Inc.
Princeton, NJ 08540

Rev. 02/2023

1325A10

N 3 0185-2098-01 7

**Mixed Salts of a Single Entity Amphetamine Product 10 mg x 100 Tablets -
Label**

NDC 0185-0842-01

**Dextroamphetamine Saccharate,
Amphetamine Aspartate,
Dextroamphetamine Sulfate and
Amphetamine Sulfate Tablets**

(Mixed Salts of A Single Entity
Amphetamine Product)

10 mg

PHARMACIST: Please dispense with
Medication Guide provided separately.

Rx Only

100 Tablets

Sandoz

NDC 0185-0842-01

**Dextroamphetamine Saccharate,
Amphetamine Aspartate,
Dextroamphetamine Sulfate and
Amphetamine Sulfate Tablets**

(Mixed Salts of A Single Entity
Amphetamine Product)

10 mg

PHARMACIST: Please dispense with
Medication Guide provided separately.

Rx Only

100 Tablets

SANDOZ

Each tablet contains: Dextroamphetamine saccharate 2.5 mg,
amphetamine aspartate monohydrate 2.5 mg, dextroamphetamine
sulfate, USP 2.5 mg and amphetamine sulfate, USP 2.5 mg.
(Total amphetamine base equivalent 6.3 mg)

USUAL ADULT DOSAGE: One tablet once or twice daily. See
accompanying literature for complete prescribing information.

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

Dispense contents in a tight, light-resistant container as
defined in the USP with a child-resistant closure, as required.
Protect from light and moisture. **KEEP TIGHTLY CLOSED.**

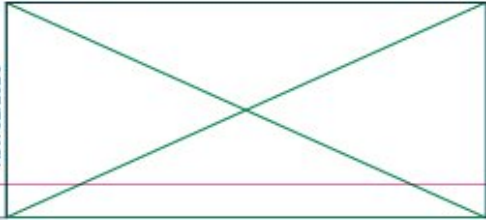
KEEP OUT OF THE REACH OF CHILDREN.

Distributed by Sandoz Inc.
Princeton, NJ 08540

1326A10

Rev. 02/2023

N 3 0185-0842-01 8



**Mixed Salts of a Single Entity Amphetamine Product 20 mg x 100 Tablets -
Label**

NDC 0185-0853-01

**Dextroamphetamine Saccharate,
Amphetamine Aspartate,
Dextroamphetamine Sulfate and
Amphetamine Sulfate Tablets**

(Mixed Salts of A Single Entity
Amphetamine Product)

20 mg

PHARMACIST: Please dispense with
Medication Guide provided separately.

Rx Only

100 Tablets

Sandoz

NDC 0185-0853-01

**Dextroamphetamine Saccharate,
Amphetamine Aspartate,
Dextroamphetamine Sulfate and
Amphetamine Sulfate Tablets**

(Mixed Salts of A Single Entity
Amphetamine Product)

20 mg

PHARMACIST: Please dispense with
Medication Guide provided separately.

Rx Only

100 Tablets

SANDOZ

Each tablet contains: Dextroamphetamine saccharate 5 mg,
amphetamine aspartate monohydrate 5 mg, dextroamphetamine
sulfate, USP 5 mg and amphetamine sulfate, USP 5 mg.
(Total amphetamine base equivalent 12.6 mg)

USUAL ADULT DOSAGE: One tablet once or twice daily. See
accompanying literature for complete prescribing information.
Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room
Temperature].

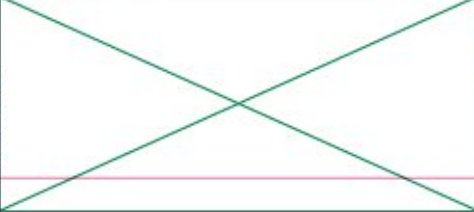
Dispense contents in a tight, light-resistant container as
defined in the USP with a child-resistant closure, as required.
Protect from light and moisture. **KEEP TIGHTLY CLOSED.**
KEEP OUT OF THE REACH OF CHILDREN.

Distributed by Sandoz Inc.
Princeton, NJ 08540

1327A10

Rev. 02/2023

N 3 0185-0853-01 4



**Mixed Salts of a Single Entity Amphetamine Product 30 mg x 100 Tablets -
Label**

NDC 0185-0864-01

**Dextroamphetamine Saccharate,
Amphetamine Aspartate,
Dextroamphetamine Sulfate and
Amphetamine Sulfate Tablets**

(Mixed Salts of A Single Entity Amphetamine Product)

30 mg

PHARMACIST: Please dispense with
Medication Guide provided separately.

Rx Only

100 Tablets

Sandoz

NDC 0185-0864-01

**Dextroamphetamine Saccharate,
Amphetamine Aspartate,
Dextroamphetamine Sulfate and
Amphetamine Sulfate Tablets**

(Mixed Salts of A Single Entity
Amphetamine Product)

30 mg

PHARMACIST: Please dispense with
Medication Guide provided separately.

Rx Only

100 Tablets

 **SANDOZ**



Each tablet contains: Dextroamphetamine saccharate 7.5 mg, amphetamine aspartate monohydrate 7.5 mg, dextroamphetamine sulfate, USP 7.5 mg and amphetamine sulfate, USP 7.5 mg. (Total amphetamine base equivalent 18.8 mg)

USUAL ADULT DOSAGE: One tablet once or twice daily. See accompanying literature for complete prescribing information. Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Dispense contents in a tight, light-resistant container as defined in the USP with a child-resistant closure, as required. Protect from light and moisture. **KEEP TIGHTLY CLOSED.**

KEEP OUT OF THE REACH OF CHILDREN.

Manufactured by Sandoz Inc.
Princeton, NJ 08540

46192677



Rev. 05/2017

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL

NDC 0185-2099-01

**Dextroamphetamine Saccharate,
Amphetamine Aspartate,
Dextroamphetamine Sulfate and
Amphetamine Sulfate Tablets**

(Mixed Salts of A Single Entity
Amphetamine Product)

30 mg

PHARMACIST: Please dispense with
Medication Guide provided separately.

Rx Only

100 Tablets

Sandoz

NDC 0185-2099-01

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

(Mixed Salts of A Single Entity
Amphetamine Product)

30 mg

PHARMACIST: Please dispense with
Medication Guide provided separately.

Rx Only

100 Tablets

SANDOZ



Each tablet contains: Dextroamphetamine saccharate 7.5 mg,
amphetamine aspartate monohydrate 7.5 mg, dextroamphetamine
sulfate, USP 7.5 mg and amphetamine sulfate, USP 7.5 mg.
(Total amphetamine base equivalent 18.8 mg)

USUAL ADULT DOSAGE: One tablet once or twice daily. See
accompanying literature for complete prescribing information.
Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room
Temperature].

Dispense contents in a tight, light-resistant container as
defined in the USP with a child-resistant closure, as required.
Protect from light and moisture. **KEEP TIGHTLY CLOSED.**

KEEP OUT OF THE REACH OF CHILDREN.

Distributed by Sandoz Inc.
Princeton, NJ 08540

1328A10

Rev. 02/2023



N 0185-2099-01 4

DEXTROAMPHETAMINE SACCHARATE, AMPHETAMINE ASPARTATE MONOHYDRATE, DEXTROAMPHETAMINE SULFATE AND AMPHETAMINE SULFATE

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

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0185-0831
Route of Administration	ORAL	DEA Schedule	CII

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROAMPHETAMINE SACCHARATE (UNII: G83415V073) (DEXTROAMPHETAMINE - UNII:TZ47U051FI)	DEXTROAMPHETAMINE SACCHARATE	1.25 mg
AMPHETAMINE ASPARTATE MONOHYDRATE (UNII: O1ZPV62004) (AMPHETAMINE - UNII:CK833KGX7E)	AMPHETAMINE ASPARTATE MONOHYDRATE	1.25 mg
DEXTROAMPHETAMINE SULFATE (UNII: JJ768O327N) (DEXTROAMPHETAMINE - UNII:TZ47U051FI)	DEXTROAMPHETAMINE SULFATE	1.25 mg
AMPHETAMINE SULFATE (UNII: 6DPV8NK46S) (AMPHETAMINE - UNII:CK833KGX7E)	AMPHETAMINE SULFATE	1.25 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics				
Color		BLUE (DARK BLUE)	Score	4 pieces
Shape		ROUND (ROUND)	Size	6mm
Flavor			Imprint Code	E;84
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0185-0831-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2016	06/30/2023
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA		ANDA040439	06/14/2002	09/30/2023

DEXTROAMPHETAMINE SACCHARATE, AMPHETAMINE ASPARTATE MONOHYDRATE, DEXTROAMPHETAMINE SULFATE AND AMPHETAMINE SULFATE

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

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0185-0842
Route of Administration	ORAL	DEA Schedule	CII
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
DEXTROAMPHETAMINE SACCHARATE (UNII: G83415V073) (DEXTROAMPHETAMINE - UNII:TZ47U051FI)		DEXTROAMPHETAMINE SACCHARATE	2.5 mg
AMPHETAMINE ASPARTATE MONOHYDRATE (UNII: O1ZPV62004) (AMPHETAMINE - UNII:CK833KGX7E)		AMPHETAMINE ASPARTATE MONOHYDRATE	2.5 mg
DEXTROAMPHETAMINE SULFATE (UNII: JJ768O327N) (DEXTROAMPHETAMINE - UNII:TZ47U051FI)		DEXTROAMPHETAMINE SULFATE	2.5 mg
AMPHETAMINE SULFATE (UNII: 6DPV8NK46S) (AMPHETAMINE - UNII:CK833KGX7E)		AMPHETAMINE SULFATE	2.5 mg
Inactive Ingredients			
Ingredient Name			Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			

STARCH, CORN (UNII: O8232NY3SJ)

Product Characteristics

Color	BLUE (DARK BLUE)	Score	4 pieces
Shape	ROUND (ROUND)	Size	8mm
Flavor		Imprint Code	E;111
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0185-0842-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040439	06/14/2002	

DEXTROAMPHETAMINE SACCHARATE, AMPHETAMINE ASPARTATE MONOHYDRATE, DEXTROAMPHETAMINE SULFATE AND AMPHETAMINE SULFATE

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

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0185-0853
Route of Administration	ORAL	DEA Schedule	CII

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROAMPHETAMINE SACCHARATE (UNII: G83415V073) (DEXTROAMPHETAMINE - UNII:TZ47U051FI)	DEXTROAMPHETAMINE SACCHARATE	5 mg
AMPHETAMINE ASPARTATE MONOHYDRATE (UNII: O1ZPV620O4) (AMPHETAMINE - UNII:CK833KGX7E)	AMPHETAMINE ASPARTATE MONOHYDRATE	5 mg
DEXTROAMPHETAMINE SULFATE (UNII: JJ768O327N) (DEXTROAMPHETAMINE - UNII:TZ47U051FI)	DEXTROAMPHETAMINE SULFATE	5 mg
AMPHETAMINE SULFATE (UNII: 6DPV8NK46S) (AMPHETAMINE - UNII:CK833KGX7E)	AMPHETAMINE SULFATE	5 mg

Inactive Ingredients

Ingredient Name	Strength
-----------------	----------

FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	ORANGE (DARK ORANGE)	Score	4 pieces
Shape	ROUND (ROUND)	Size	8mm
Flavor		Imprint Code	E;401
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0185-0853-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040439	06/14/2002	

DEXTROAMPHETAMINE SACCHARATE, AMPHETAMINE ASPARTATE MONOHYDRATE, DEXTROAMPHETAMINE SULFATE AND AMPHETAMINE SULFATE

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

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0185-0864
Route of Administration	ORAL	DEA Schedule	CII

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROAMPHETAMINE SACCHARATE (UNII: G83415V073) (DEXTROAMPHETAMINE - UNII:TZ47U051FI)	DEXTROAMPHETAMINE SACCHARATE	7.5 mg
AMPHETAMINE ASPARTATE MONOHYDRATE (UNII: O1ZPV62004) (AMPHETAMINE - UNII:CK833KGX7E)	AMPHETAMINE ASPARTATE MONOHYDRATE	7.5 mg
DEXTROAMPHETAMINE SULFATE (UNII: JJ768O327N) (DEXTROAMPHETAMINE - UNII:TZ47U051FI)	DEXTROAMPHETAMINE SULFATE	7.5 mg
AMPHETAMINE SULFATE (UNII: 6DPV8NK46S) (AMPHETAMINE - UNII:CK833KGX7E)	AMPHETAMINE SULFATE	7.5 mg

Inactive Ingredients				
Ingredient Name			Strength	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)				
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
STARCH, CORN (UNII: O8232NY3SJ)				
Product Characteristics				
Color	ORANGE (DARK ORANGE)	Score	4 pieces	
Shape	ROUND (ROUND)	Size	11mm	
Flavor		Imprint Code	E;404	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0185-0864-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2016	09/30/2023
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA		ANDA040439	06/14/2002	09/30/2023

DEXTROAMPHETAMINE SACCHARATE, AMPHETAMINE ASPARTATE MONOHYDRATE, DEXTROAMPHETAMINE SULFATE AND AMPHETAMINE SULFATE			
dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate tablet			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0185-2099
Route of Administration	ORAL	DEA Schedule	CII
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
DEXTROAMPHETAMINE SACCHARATE (UNII: G83415V073) (DEXTROAMPHETAMINE - UNII:TZ47U051FI)		DEXTROAMPHETAMINE SACCHARATE	7.5 mg
AMPHETAMINE ASPARTATE MONOHYDRATE (UNII: O1ZPV62004) (AMPHETAMINE - UNII:CK833KGX7E)		AMPHETAMINE ASPARTATE MONOHYDRATE	7.5 mg
DEXTROAMPHETAMINE SULFATE (UNII: JJ768O327N) (DEXTROAMPHETAMINE - UNII:TZ47U051FI)		DEXTROAMPHETAMINE SULFATE	7.5 mg
AMPHETAMINE SULFATE (UNII: CDDVONK16C) (AMPHETAMINE			

AMPHETAMINE SULFATE (UNII: 6DPV8NK46S) (AMPHETAMINE - UNII:CK833KGX7E)		AMPHETAMINE SULFATE	7.5 mg	
Inactive Ingredients				
Ingredient Name			Strength	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)				
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
STARCH, CORN (UNII: O8232NY3SJ)				
Product Characteristics				
Color	ORANGE (DARK ORANGE)	Score	4 pieces	
Shape	ROUND (ROUND)	Size	10mm	
Flavor		Imprint Code	E;404	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0185-2099-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/16/2021	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
ANDA	ANDA040439		06/14/2002	

DEXTROAMPHETAMINE SACCHARATE, AMPHETAMINE ASPARTATE MONOHYDRATE, DEXTROAMPHETAMINE SULFATE AND AMPHETAMINE SULFATE dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate tablet			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0185-2098
Route of Administration	ORAL	DEA Schedule	CII
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
DEXTROAMPHETAMINE SACCHARATE (UNII: G83415V073) (DEXTROAMPHETAMINE - UNII:TZ47U051FI)		DEXTROAMPHETAMINE SACCHARATE	1.25 mg
AMPHETAMINE ASPARTATE MONOHYDRATE (UNII: O1ZPV62004)		AMPHETAMINE ASPARTATE	1.25 mg

(AMPHETAMINE - UNII:CK833KGX7E)	MONOHYDRATE	1.25 mg
DEXTROAMPHETAMINE SULFATE (UNII: JJ768O327N) (DEXTROAMPHETAMINE - UNII:TZ47U051FI)	DEXTROAMPHETAMINE SULFATE	1.25 mg
AMPHETAMINE SULFATE (UNII: 6DPV8NK46S) (AMPHETAMINE - UNII:CK833KGX7E)	AMPHETAMINE SULFATE	1.25 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	BLUE (DARK BLUE)	Score	4 pieces
Shape	ROUND (ROUND)	Size	6mm
Flavor		Imprint Code	E;84
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0185-2098-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/08/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040439	06/14/2002	

Labeler - Sandoz Inc (005387188)