DEXTROAMPHETAMINE SULFATE EXTENDED-RELEASE- dextroamphetamine sulfate capsule, extended release
SpecGx LLC

Dextroamphetamine Sulfate Extended-Release Capsules, CII

Rx only

WARNING: ABUSE, MISUSE, AND ADDICTION

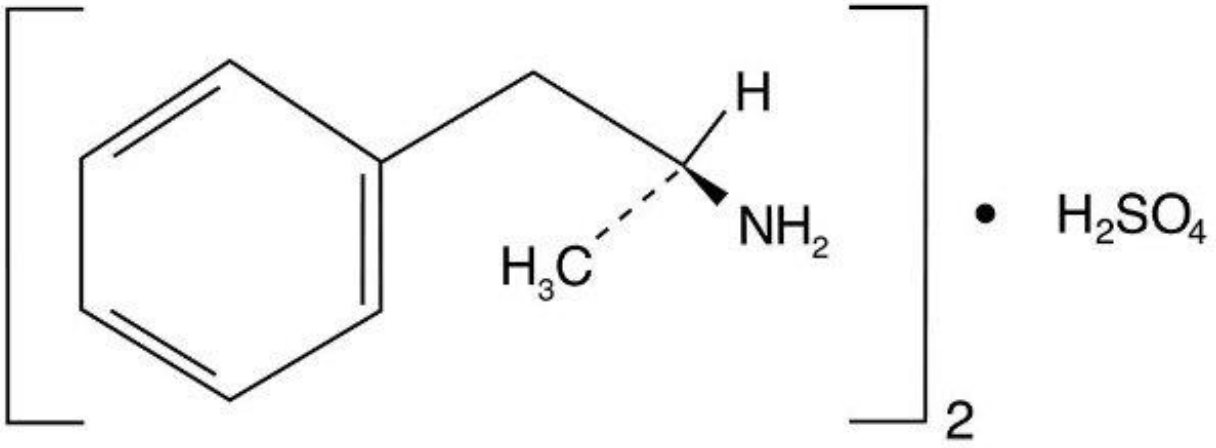
Dextroamphetamine sulfate extended-release capsules have a high potential for abuse and misuse, which can lead to the development of a substance use disorder, including addiction. Misuse and abuse of CNS stimulants, including dextroamphetamine sulfate extended-release capsules, can result in overdose 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 sulfate extended-release capsules, 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 sulfate extended-release capsules 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

Dextroamphetamine sulfate extended-release capsule is the dextro isomer of the compound *d,l*-amphetamine sulfate, a sympathomimetic amine of the amphetamine group. Chemically, dextroamphetamine is *d*-alpha-methylphenethylamine, and is present in all forms of dextroamphetamine sulfate extended-release capsules as the neutral sulfate.

Structural formula:



Dextroamphetamine Sulfate Extended-Release Capsules

Each dextroamphetamine sulfate extended-release capsule is so prepared that an initial dose is released promptly and the remaining medication is released gradually over a prolonged period.

Each capsule, with white opaque cap and white opaque body, contains dextroamphetamine sulfate USP. The 5 mg capsule is imprinted with an M® on the cap and is imprinted 8960 5 mg on the body in black. The 10 mg capsule is imprinted with an M® on the cap and is imprinted 8961 10 mg on the body in blue. The 15 mg capsule is imprinted with an M® on the cap and is imprinted 8962 15 mg on the body in pink. Inactive ingredients consist of sugar spheres, titanium dioxide, gelatin, shellac glaze-45%, SD-45 alcohol, iron oxide black, propylene glycol, FD&C Blue #2/Indigo Carmine Lake, FD&C Red #40/Allura Red AC Lake, FD&C Blue #1/Brilliant Blue FCF Lake, D&C Yellow #10 Lake, SD3A alcohol, shellac, dehydrated alcohol, isopropyl alcohol, butyl alcohol, strong ammonia solution, FD&C Blue #2 Aluminum Lake, D&C Red #7 Calcium Lake, hydroxypropyl methylcellulose/hypromellose, macrogol/polyethylene glycol, purified water, ethylcellulose, ammonium hydroxide 28%, medium chain triglycerides, oleic acid.

CLINICAL PHARMACOLOGY

Amphetamines are noncatecholamine, sympathomimetic amines with CNS stimulant activity. Peripheral actions include elevations of systolic and diastolic blood pressures and weak bronchodilator and respiratory stimulant action. There is neither specific evidence that clearly establishes the mechanism whereby amphetamines produce mental and behavioral effects in children, nor conclusive evidence regarding how these effects relate to the condition of the central nervous system. Dextroamphetamine sulfate extended-release capsules are formulated to release the active drug substance in vivo in a more gradual fashion than the standard formulation, as demonstrated by blood levels. The formulation has not been shown superior in effectiveness over the same dosage of the standard, noncontrolled-release formulations given in divided doses.

Pharmacokinetics

The pharmacokinetics of the tablet and sustained-release capsule were compared in 12 healthy subjects. The extent of bioavailability of the sustained-release capsule was

similar compared to the immediate-release tablet. Following administration of three 5 mg tablets, average maximal dextroamphetamine plasma concentrations (C_{max}) of 36.6 ng/mL were achieved at approximately 3 hours.

Following administration of one 15 mg sustained-release capsule, maximal dextroamphetamine plasma concentrations were obtained approximately 8 hours after dosing. The average C_{max} was 23.5 ng/mL. The average plasma $T_{1/2}$ was similar for both the tablet and sustained-release capsule and was approximately 12 hours. In 12 healthy subjects, the rate and extent of dextroamphetamine absorption were similar following administration of the sustained-release capsule formulation in the fed (58 g to 75 g fat) and fasted state.

INDICATIONS AND USAGE

Dextroamphetamine sulfate extended-release capsules are indicated in:

Narcolepsy

Attention Deficit Disorder with Hyperactivity

As an integral part of a total treatment program that typically includes other measures (psychological, educational, social) for patients (ages 6 years to 16 years) with this syndrome. A diagnosis of Attention Deficit Hyperactivity Disorder (ADHD; DSM-IV) implies the presence of the 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 2 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 6 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 6 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 of medical and 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 patient and not solely on the presences of the required number of DSM-IV characteristics.

Need for Comprehensive Treatment Program

Dextroamphetamine sulfate extended-release capsules 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 patients with this syndrome. Stimulants are not intended for use in patients who exhibit 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 patient's symptoms.

CONTRAINDICATIONS

In patients known to be hypersensitive to amphetamine, or other components of dextroamphetamine sulfate extended-release capsules. 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 sulfate extended-release capsules have a high potential for abuse and misuse. The use of dextroamphetamine sulfate extended-release capsules exposes individuals to the risks of abuse and misuse, which can lead to the development of a substance use disorder, including addiction. Dextroamphetamine sulfate extended-release capsules can be diverted for non-medical use into illicit channels or distribution (*see* **DRUG ABUSE AND DEPENDENCE**). Misuse and abuse of CNS stimulants, including dextroamphetamine sulfate extended-release capsules, 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 sulfate extended-release capsules, 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 sulfate extended-release capsules to anyone else. Throughout dextroamphetamine sulfate extended-release capsules 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 are treated with CNS stimulants at the recommended ADHD dosages.

Avoid dextroamphetamine sulfate extended-release capsule 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).

Monitor all patients for potential tachycardia and hypertension.

Psychiatric Adverse Reactions

Exacerbation of Pre-Existing Psychosis

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

Induction of a Manic Episode in Patients with Bipolar Disease

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 sulfate extended-release capsules.

Long-Term Suppression of Growth in Pediatric Patients

CNS stimulants have been associated with weight loss and slowing of growth rate in pediatric patients, including dextroamphetamine sulfate extended-release capsules. Closely monitor growth (weight and height) in dextroamphetamine sulfate extended-release capsules-treated pediatric patients treated with CNS stimulants.

Pediatric patients who are not growing or gaining height or 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 seizures, 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 sulfate extended-release capsules, used to treat ADHD are associated with peripheral vasculopathy, including Raynaud’s phenomenon. Signs and symptoms are usually intermittent and mild; however, sequelae have included digital ulceration and/or soft tissue breakdown. Effects of peripheral vasculopathy, including Raynaud’s phenomenon, were observed in postmarketing reports and at therapeutic dosages in all age groups throughout the course of treatment. Signs and symptoms generally improve after dosage reduction or discontinuation of the CNS stimulant. Careful observation for digital changes is necessary during dextroamphetamine sulfate extended-release capsules treatment. Further clinical evaluation (e.g., rheumatology referral) may be appropriate for dextroamphetamine sulfate extended-release capsules-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**). 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 co-administration of CYP2D6 inhibitors which may increase the risk with increased exposure to dextroamphetamine sulfate extended-release capsules. 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 sulfate extended-release capsules with MAOI drugs is contraindicated (*see* **CONTRAINDICATIONS**).

Discontinue treatment with dextroamphetamine sulfate extended-release capsules and any concomitant serotonergic agents immediately if the above symptoms occur, and initiate supportive symptomatic treatment. If concomitant use of dextroamphetamine sulfate extended-release capsules with other serotonergic drugs or CYP2D6 inhibitors is clinically warranted, initiate dextroamphetamine sulfate extended-release capsules 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 sulfate extended-release capsules, 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 sulfate extended-release capsules, and discontinue treatment if clinically appropriate.

PRECAUTIONS

General

The least amount feasible should be prescribed or dispensed at one time in order to minimize the possibility of overdosage.

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 sulfate extended-release capsules, 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 sulfate extended-release capsules in a safe place, preferably locked, and instruct patients to not give dextroamphetamine sulfate extended-release capsules 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 sulfate extended-release capsules 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

Instruct patients that dextroamphetamine sulfate extended-release capsules can elevate blood pressure and heart rate (*see* **WARNINGS**).

Psychiatric Adverse Reactions

Advise patients that dextroamphetamine sulfate extended-release capsules, 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 sulfate extended-release capsules may cause slowing of growth and weight loss in pediatric patients (*see* **WARNINGS**).

Circulation problems in fingers and toes [Peripheral vasculopathy, including Raynaud's phenomenon]

- Instruct patients beginning treatment with dextroamphetamine sulfate extended-release capsules 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 sulfate extended-release capsules.
- Further clinical evaluation (e.g., rheumatology referral) may be appropriate for certain patients (*see* **WARNINGS**).

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 sulfate extended-release capsules. Instruct the patients to notify their healthcare provider if emergence or worsening of tics or Tourette's syndrome occurs (*see* **WARNINGS**).

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, glutamic 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 sulfate extended-release capsules 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 sulfate extended-release capsules and CYP2D6 inhibitors may increase the exposure of dextroamphetamine sulfate extended-release capsules 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 sulfate extended-release capsules initiation and after a dosage increase. If serotonin syndrome occurs, discontinue dextroamphetamine sulfate extended-release capsules 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 sulfate extended-release capsules 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 sulfate extended-release capsules initiation or dosage increase. If serotonin syndrome occurs, discontinue dextroamphetamine sulfate extended-release capsules 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 sulfate extended-release capsules concomitantly or within 14 days after discontinuing MAOI (*see* **CONTRAINDICATIONS** *and* **WARNINGS**). Examples of MAOIs include selegiline, tranylcypromine, isocarboxazid, phenelzine, linezolid, methylene blue.

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.

Antihistamines

Amphetamines may counteract the sedative effect of antihistamines.

Antihypertensives

Amphetamines may antagonize the hypotensive effects of antihypertensives.

Chlorpromazine

Chlorpromazine blocks dopamine and norepinephrine reuptake, 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 and norepinephrine reuptake, thus inhibiting the central stimulant effects of amphetamines.

Lithium Carbonate

The 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; co-administration of phenobarbital may produce a synergistic anticonvulsant action.

Phenytoin

Amphetamines may delay intestinal absorption of phenytoin; co-administration of phenytoin may produce a synergistic anticonvulsant action.

Propoxyphene

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

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

Mutagenicity studies and long-term studies in animals to determine the carcinogenic potential of dextroamphetamine sulfate extended-release capsules have not been performed.

Pregnancy

Teratogenic Effects

Dextroamphetamine sulfate extended-release capsules have been shown to have embryotoxic and teratogenic effects when administered to A/Jax mice and C57BL mice in doses approximately 41 times the maximum human dose. Embryotoxic effects were not seen in New Zealand white rabbits given the drug in doses 7 times the human dose nor in rats given 12.5 times the maximum human dose. While there are no adequate and well-controlled studies in pregnant women, there has been one report of severe congenital bony deformity, tracheoesophageal 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. Dextroamphetamine sulfate extended-release capsules 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.

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 pediatric patients have not been well established.

Dextroamphetamine sulfate extended-release capsules are not recommended for use in pediatric patients younger than 6 years of age with Attention Deficit Disorder with Hyperactivity described under **INDICATIONS AND USAGE**.

Clinical experience suggests that in psychotic children, administration of amphetamines may exacerbate symptoms of behavior disturbance and thought disorder.

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.

Data are inadequate to determine whether chronic administration of amphetamines may be associated with growth inhibition; therefore, growth should be monitored during treatment.

Drug treatment is not indicated in all cases of Attention Deficit Disorder with Hyperactivity and should be considered only in light of the complete history and evaluation of the child. The decision to prescribe amphetamines should depend on the physician's assessment of the chronicity and severity of the child's symptoms and their appropriateness for his or her age. Prescription should not depend solely on the presence of one or more of the behavioral characteristics.

When these symptoms are associated with acute stress reactions, treatment with amphetamines is usually not indicated.

ADVERSE REACTIONS

Cardiovascular

Palpitations, tachycardia, elevation of blood pressure. There have been isolated reports of cardiomyopathy associated with chronic amphetamine use.

Central Nervous System

Psychotic episodes at recommended doses (rare), overstimulation, restlessness, dizziness, insomnia, euphoria, dyskinesia, dysphoria, tremor, headache, exacerbation of motor and verbal tics and Tourette's syndrome.

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.

Endocrine

Impotence, changes in libido, frequent or prolonged erections.

Musculoskeletal

Rhabdomyolysis.

Skin and Subcutaneous Tissue Disorders

Alopecia.

To report SUSPECTED ADVERSE REACTIONS, contact Mallinckrodt at 1-800-778-7898 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG ABUSE AND DEPENDENCE

Controlled Substance

Dextroamphetamine sulfate extended-release capsules contain dextroamphetamine, a Schedule II controlled substance.

Abuse

Dextroamphetamine sulfate extended-release capsules have a high potential for abuse and misuse which can lead to the development of a substance use disorder, including addiction (*see* **WARNINGS**). Dextroamphetamine sulfate extended-release capsules 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 healthcare 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 amphetamine 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 sulfate extended-release capsules, 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 sulfate extended-release capsules 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 sulfate extended-release capsules include dysphoric mood; depression; fatigue; vivid,

unpleasant dreams; insomnia or hypersomnia; increased appetite; and psychomotor retardation or agitation.

Tolerance

Dextroamphetamine sulfate extended-release capsules 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. The pharmacokinetic profile of dextroamphetamine sulfate extended-release capsules should be considered when treating patients with overdose. 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

Amphetamines should be administered at the lowest effective dosage and dosage should be individually adjusted. Late evening doses should be avoided because of the resulting insomnia.

Prior to treating patients with dextroamphetamine sulfate extended-release capsules, 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 (*see* **WARNINGS**).

Narcolepsy

Usual dose is 5 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 extended-release capsules 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 an 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 an optimal response is obtained. If bothersome adverse reactions appear (e.g., insomnia or anorexia), dosage should be reduced. Dextroamphetamine sulfate extended-release capsules may be used for once-a-day dosage wherever appropriate.

Attention Deficit Disorder with Hyperactivity

The dextroamphetamine sulfate extended-release capsule formulation is not recommended for pediatric patients younger than 6 years of age.

In pediatric patients 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. Dextroamphetamine sulfate extended-release capsules may be used for once-a-day dosage wherever appropriate.

HOW SUPPLIED

Dextroamphetamine Sulfate Extended-Release Capsules

Each capsule, with white opaque cap and white opaque body, contains dextroamphetamine sulfate.

The 5 mg capsule is imprinted with an M® on the cap and is imprinted 8960 5 mg on the body in black.

The 10 mg capsule is imprinted with an M® on the cap and is imprinted 8961 10 mg on the body in blue.

The 15 mg capsule is imprinted with an M® on the cap and is imprinted 8962 15 mg on the body in pink.

5 mg	Bottles of 100	NDC 0406-8960-01
10 mg	Bottles of 100	NDC 0406-8961-01
15 mg	Bottles of 100	NDC 0406-8962-01

Store at controlled room temperature between 20° to 25°C (68° to 77°F) [see USP].

Dispense in a tight, light-resistant container with a child-resistant closure.

SpecGx LLC
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Rev 10/2023

Mallinckrodt™
Pharmaceuticals

An electronic copy of this medication guide can be obtained from

www.mallinckrodt.com/Medguide/L20D09.pdf or by calling 1-800-778-7898 for alternate delivery options.

MEDICATION GUIDE
Dextroamphetamine Sulfate Extended-Release Capsules, CII
(DEX-troe-am-FET-uh-meen SULL-fate)

What is the most important information I should know about dextroamphetamine sulfate extended-release capsules?
Dextroamphetamine sulfate extended-release capsules may cause serious side effects, including:

- **Abuse misuse, and addiction.** Dextroamphetamine sulfate extended-release capsules have a high chance for abuse and misuse and may lead to substance use problems, including addiction. Misuse and abuse of dextroamphetamine sulfate extended-release capsules, 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 dextroamphetamine sulfate extended-release capsules or when they are used in ways that are not approved, such as snorting or injection.
  - Your healthcare provider should check you or your child's risk for abuse, misuse, and addiction before starting treatment with dextroamphetamine sulfate extended-release capsules and will monitor you or your child during treatment.
  - Dextroamphetamine sulfate extended-release capsules may lead to physical dependence after prolonged use, even if taken as directed by your healthcare provider.
  - Do not give dextroamphetamine sulfate extended-release capsules to anyone else. See **"What are dextroamphetamine sulfate extended-release capsules?"** for more information.
  - Keep dextroamphetamine sulfate extended-release capsules in a safe place and properly dispose of any unused medicine. See **"How should I store dextroamphetamine sulfate extended-release capsules?"** for more information.
  - Tell your healthcare provider if you or your child have ever abused or been dependent on alcohol, prescription medicines, or street drugs.

- **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 dextroamphetamine sulfate extended-release capsules. 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 dextroamphetamine sulfate extended-release capsules.

- **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 dextroamphetamine sulfate extended-release capsules.

- **Mental (psychiatric) problems, including:**
  - new or worse behavior or thought problems
  - new or worse bipolar illness
  - 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 dextroamphetamine sulfate extended-release capsules, especially hearing voices, seeing or believing things that are not real, or new manic symptoms.

What are dextroamphetamine sulfate extended-release capsules?
Dextroamphetamine sulfate extended-release capsules are a central nervous system (CNS) stimulant prescription medicine used for the treatment of:
- a sleep disorder called narcolepsy.
- Attention-Deficit Hyperactivity Disorder (ADHD) in children 6 to 17 years of age.
- dextroamphetamine sulfate extended-release capsules may help increase attention and decrease impulsiveness and hyperactivity in people with ADHD.

It is not known if dextroamphetamine sulfate extended-release capsules are safe and effective in children under 6 years of age.
Dextroamphetamine sulfate extended-release capsules are a federally controlled substance (CII) because they contain dextroamphetamine that can be a target for people who abuse prescription medicines or street drugs. Keep dextroamphetamine sulfate extended-release capsules in a safe place to protect them from theft. Never give your dextroamphetamine sulfate extended-release capsules to anyone else because they may cause death or harm them. Selling or giving away dextroamphetamine sulfate extended-release capsules may harm others and is against the law.

Do not take dextroamphetamine sulfate extended-release capsules if you or your child:
- are allergic to amphetamine products or any of the ingredients in dextroamphetamine sulfate extended-release capsules. See the end of this Medication Guide for a complete list of ingredients in dextroamphetamine sulfate extended-release capsules.
- 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 dextroamphetamine sulfate extended-release capsules, 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 seizures or have had an abnormal brain wave test (EEG)
- have circulation problems in fingers and 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 dextroamphetamine sulfate extended-release capsules will harm the unborn baby. Tell your healthcare provider if you or your child become pregnant during treatment with dextroamphetamine sulfate extended-release capsules.
- are breastfeeding or plan to breastfeed. Dextroamphetamine sulfate extended-release capsules pass into breast milk. You or your child should not breastfeed during treatment with dextroamphetamine sulfate extended-release capsules. Talk to your healthcare provider about the best way to feed the baby during treatment with dextroamphetamine sulfate extended-release capsules.

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.
Dextroamphetamine sulfate extended-release capsules 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 dextroamphetamine sulfate extended-release capsules. Your healthcare provider will decide if dextroamphetamine sulfate extended-release capsules can be taken with other medicines.
Especially tell your healthcare provider if you or your child take:
- selective serotonin reuptake inhibitors (SSRIs)
- serotonin norepinephrine reuptake inhibitors (SNRIs)
- medicines used to treat migraine headaches called triptans
- tricyclic antidepressants
- lithium
- fentanyl
- tramadol
- tryptophan
- buspirone
- 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 dextroamphetamine sulfate extended-release capsules without talking to your healthcare provider first.

How should dextroamphetamine sulfate extended-release capsules be taken?
- Take dextroamphetamine sulfate extended-release capsules exactly as prescribed by your or your child’s healthcare provider.
- Your healthcare provider may change the dose if needed.
- Dextroamphetamine sulfate extended-release capsules are an extended-release capsule. They release medicine into your body throughout the day.

If you or your child take too many dextroamphetamine sulfate extended-release capsules, 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 dextroamphetamine sulfate extended-release capsules?
Dextroamphetamine sulfate extended-release capsules may cause serious

side effects, including:

- See **"What is the most important information I should know about dextroamphetamine sulfate extended-release capsules?"**
- **Slowing of growth (height and weight) in children.** Children should have their height and weight checked often during treatment with dextroamphetamine sulfate extended-release capsules. Your healthcare provider may stop your child's dextroamphetamine sulfate extended-release capsules treatment if they are not growing or gaining weight as expected.
- **Seizures.** Your healthcare provider may stop treatment with dextroamphetamine sulfate extended-release capsules 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:**
- Fingers or toes may feel numb, cool, painful
- Fingers or toes may change color from pale, to blue, to red

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

  Call your healthcare provider right away if you or your child have any signs of unexplained wounds appearing on fingers or toes during treatment with dextroamphetamine sulfate extended-release capsules.
- **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 dextroamphetamine sulfate extended-release capsules.
- **Serotonin syndrome.** This problem may happen when dextroamphetamine sulfate extended-release capsules are taken with certain other medicines and may be life-threatening. Stop taking dextroamphetamine sulfate extended-release capsules 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
  - fast heartbeat
  - flushing
  - seizures
  - coma
  - sweating
  - loss of coordination
  - confusion
  - dizziness
  - tremors, stiff muscles, or muscle twitching
  - seeing or hearing things that are not real (hallucination)
  - changes in blood pressure
  - high body temperature (hypothermia)
  - nausea, vomiting, diarrhea

The most common side effects of dextroamphetamine sulfate extended-release capsules include:

- fast heartbeat
- decreased appetite
- tremors

- headache
- trouble sleeping
- dizziness
- stomach upset
- weight loss
- dry mouth

These are not all of the possible side effects of dextroamphetamine sulfate extended-release capsules. 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 sulfate extended-release capsules?

- Store dextroamphetamine sulfate extended-release capsules at room temperature between 68° to 77°F (20° to 25°C).
- Store dextroamphetamine sulfate extended-release capsules in a safe place, like a locked cabinet. Protect from light.
- Dispose of remaining, unused, or expired dextroamphetamine sulfate extended-release capsules 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 dextroamphetamine sulfate extended-release capsules 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 dextroamphetamine sulfate extended-release capsules in the household trash. Visit www.fda.gov/drugdisposal for additional information on disposal of unused medicines.

Keep dextroamphetamine sulfate extended-release capsules and all medicines out of the reach of children.

General information about the safe and effective use of dextroamphetamine sulfate extended-release capsules.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use dextroamphetamine sulfate extended-release capsules for a condition for which they were not prescribed. Do not give dextroamphetamine sulfate extended-release capsules to other people, even if they have the same symptoms that you or your child have. It may harm them and it is against the law. You can ask your pharmacist or healthcare provider for information about dextroamphetamine sulfate extended-release capsules that is written for healthcare professionals.

What are the ingredients in dextroamphetamine sulfate extended-release capsules?

Active ingredient: dextroamphetamine sulfate USP

Inactive ingredients: sugar spheres, titanium dioxide, gelatin, shellac glaze-45%, SD-45 alcohol, iron oxide black, propylene glycol, FD&C Blue #2/Indigo Carmine Lake, FD&C Red #40/Allura Red AC Lake, FD&C Blue #1/Brilliant Blue FCF Lake, D&C Yellow #10 Lake, SD3A alcohol, shellac, dehydrated alcohol, isopropyl alcohol, butyl alcohol, strong ammonia solution, FD&C Blue #2 Aluminum Lake, D&C Red #7 Calcium Lake, hydroxypropyl methylcellulose/hypromellose, macrogol/polyethylene glycol, purified water, ethylcellulose, ammonium hydroxide 28%, medium chain triglycerides, oleic acid.

Manufactured by:
SpecGx LLC
Webster Groves, MO 63119 USA

For more information about dextroamphetamine sulfate extended-release capsules, visit

www.mallinckrodt.com or call 1-800-778-7898.
Mallinckrodt™

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

Rev 10/2023
L20D09

PACKAGE LABEL - PRINCIPAL DISPLAY PANEL - 5 mg capsule

NDC 0406-8960-01

100 CAPSULES

Dextroamphetamine Sulfate
Extended-Release Capsules

CII

5 mg

Rx only

Each capsule contains:
Dextroamphetamine Sulfate USP..... 5 mg

PHARMACIST: Dispense the Medication Guide provided separately to each patient.

Mallinckrodt™

L00D35

Rev 09/2017

PACKAGE LABEL - PRINCIPAL DISPLAY PANEL - 10 mg capsule

NDC 0406-8961-01

100 CAPSULES

Dextroamphetamine Sulfate
Extended-Release Capsules

CII

10 mg

Rx only

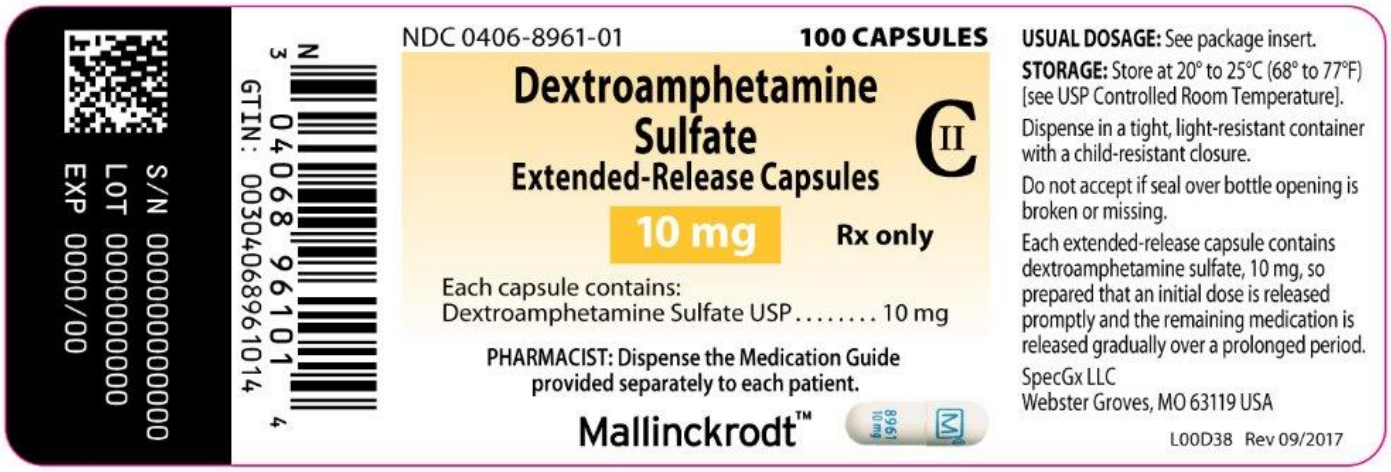
Each capsule contains:
Dextroamphetamine Sulfate USP..... 10 mg

PHARMACIST: Dispense the Medication Guide provided separately to each patient.

Mallinckrodt™

L00D38

Rev 09/2017



PACKAGE LABEL - PRINCIPAL DISPLAY PANEL - 15 mg capsule

NDC 0406-8962-01

100 CAPSULES

Dextroamphetamine Sulfate
Extended-Release Capsules

CII

15 mg

Rx only

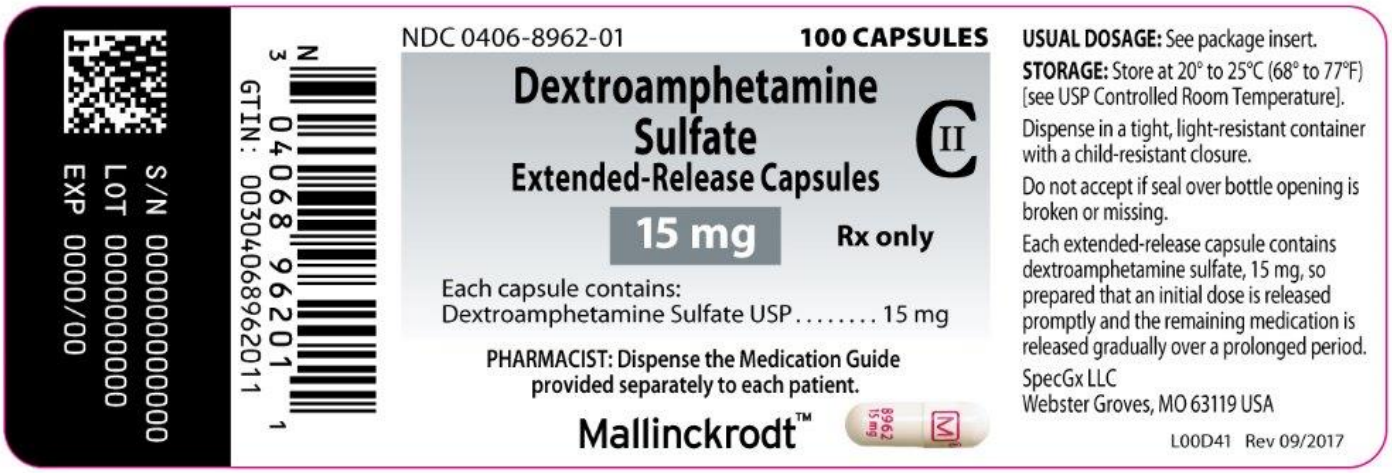
Each capsule contains:
Dextroamphetamine Sulfate USP..... 15 mg

PHARMACIST: Dispense the Medication Guide provided separately to each patient.

Mallinckrodt™

L00D41

Rev 09/2017



DEXTROAMPHETAMINE SULFATE EXTENDED-RELEASE

dextroamphetamine sulfate capsule, extended release

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0406-8960
Route of Administration	ORAL	**DEA Schedule**	CII

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DEXTROAMPHETAMINE SULFATE (UNII: JJ768O327N) (DEXTROAMPHETAMINE - UNII:TZ47U051FI)	DEXTROAMPHETAMINE SULFATE	5 mg

Inactive Ingredients	
Ingredient Name	**Strength**
SUCROSE (UNII: C151H8M554)	
CORN STARCH 3-E-DODECENYL SUCCINIC ANHYDRIDE MODIFIED (UNII: QG4MW19XYX)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	

FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
ALCOHOL (UNII: 3K9958V90M)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
AMMONIA (UNII: 5138Q19F1X)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSE 2208 (100000 MPA.S) (UNII: VM7F0B23ZI)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
WATER (UNII: 059QF0KO0R)	
ETHYLCELLULOSE, UNSPECIFIED (UNII: 7Z8S9VYZ4B)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
OLEIC ACID (UNII: 2UMI9U37CP)	

Product Characteristics

Color	white (white)	**Score**	no score
Shape	CAPSULE (capsule)	**Size**	14mm
Flavor		**Imprint Code**	M;8960;5;mg
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0406-8960-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/06/2003	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076353	05/06/2003	

DEXTROAMPHETAMINE SULFATE EXTENDED-RELEASE

dextroamphetamine sulfate capsule, extended release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0406-8961
Route of Administration	ORAL	**DEA Schedule**	CII

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROAMPHETAMINE SULFATE (UNII: JJ768O327N) (DEXTROAMPHETAMINE - UNII:TZ47U051FI)	DEXTROAMPHETAMINE SULFATE	10 mg

Inactive Ingredients

Ingredient Name	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
SHELLAC (UNII: 46N107B71O)	
ALCOHOL (UNII: 3K9958V90M)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
AMMONIA (UNII: 5138Q19F1X)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
WATER (UNII: 059QF0KO0R)	
ETHYLCELLULOSE, UNSPECIFIED (UNII: 7Z8S9VYZ4B)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
OLEIC ACID (UNII: 2UMI9U37CP)	

Product Characteristics

Color	white (white)	**Score**	no score
Shape	CAPSULE (capsule)	**Size**	14mm
Flavor		**Imprint Code**	M;8961;10;mg
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0406-8961-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/06/2003	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076353	05/06/2003	

DEXTROAMPHETAMINE SULFATE EXTENDED-RELEASE

dextroamphetamine sulfate capsule, extended release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0406-8962
Route of Administration	ORAL	**DEA Schedule**	CII

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROAMPHETAMINE SULFATE (UNII: JJ768O327N) (DEXTROAMPHETAMINE - UNII:TZ47U051FI)	DEXTROAMPHETAMINE SULFATE	15 mg

Inactive Ingredients

Ingredient Name	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
SHELLAC (UNII: 46N107B71O)	
ALCOHOL (UNII: 3K9958V90M)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
AMMONIA (UNII: 5138Q19F1X)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
WATER (UNII: 059QF0KO0R)	
ETHYLCELLULOSE, UNSPECIFIED (UNII: 7Z8S9VYZ4B)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
OLEIC ACID (UNII: 2UMI9U37CP)	

Product Characteristics

Color	white (white)	**Score**	no score
Shape	CAPSULE (capsule)	**Size**	16mm
Flavor		**Imprint Code**	M;8962;15;mg
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0406-8962-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/06/2003	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076353	05/06/2003	

Labeler - SpecGx LLC (080679498)

Establishment

Name	Address	ID/FEI	Business Operations
SpecGx LLC		957414238	analysis(0406-8960, 0406-8961, 0406-8962) , manufacture(0406-8960, 0406-8961, 0406-8962)

Establishment

Name	Address	ID/FEI	Business Operations
SpecGx LLC		163205300	api manufacture(0406-8960, 0406-8961, 0406-8962)

Revised: 7/2024 SpecGx LLC