DEXTROAMPHETAMINE SULFATE- dextroamphetamine sulfate capsule, extended release
Actavis Pharma, Inc.

Dextroamphetamine Sulfate Extended-Release Capsules CII

Rx only

WARNING: ABUSE, MISUSE, AND ADDICTION

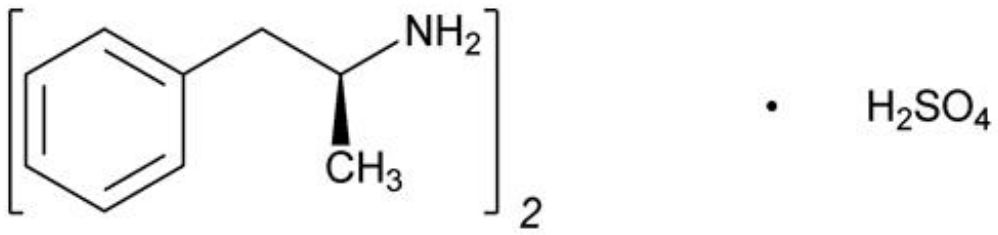
Dextroamphetamine sulfate extended-release capsule has a high potential for abuse and misuse, which can lead to the development of a substance use disorder, including addiction. Misuse and abuse of CNS stimulants, including dextroamphetamine sulfate extended-release capsules, can result in overdose and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

Structural formula:



Each 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 5 mg capsule, with a light brown opaque cap and body, contains 5 mg of dextroamphetamine sulfate, USP. The 5 mg capsule is printed with  and 0303 on both cap and body in black ink.

Each 10 mg capsule, with a light brown opaque cap and light orange transparent body, contains 10 mg of dextroamphetamine sulfate, USP. The 10 mg capsule is printed with  and 0304 on both cap and body in black ink.

Each 15 mg capsule, with a light brown opaque cap and light orange transparent body, contains 15 mg of dextroamphetamine sulfate, USP. The 15 mg capsule is printed with  and 0305 on both cap and body in black ink.

Inactive ingredients: denatured alcohol, ammonium hydroxide, ethylcellulose, gelatin, hydroxypropyl cellulose, hypromellose, medium chain triglycerides, oleic acid, polyethylene glycol and sugar spheres (which contain sucrose and corn starch).

The capsule shells of the 5 mg, 10 mg and 15 mg contain black iron oxide, red iron oxide, silicon dioxide, sodium lauryl sulfate, talc, titanium dioxide and yellow iron oxide. In addition, the 10 mg and 15 mg capsule shell contains FD&C Red #40 and D&C Yellow #10.

The capsule shells are imprinted with black ink which contains: ammonium hydroxide, black iron oxide, butyl alcohol, dehydrated alcohol, isopropyl alcohol, potassium hydroxide, propylene glycol, purified water, shellac, and strong ammonia solution.

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 extended-release capsule were compared in 12 healthy subjects. The extent of bioavailability of the extended-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 extended-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 extended-release capsule and was approximately 12 hours. In 12

healthy subjects, the rate and extent of dextroamphetamine absorption were similar following administration of the extended-release capsule formulation in the fed (58 gm to 75 gm 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 is 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. 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 capsule has 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
pre-existing 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, consideration discontinuing dextroamphetamine sulfate extended-release.

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. Closely monitor growth (weight and height) in dextroamphetamine sulfate extended-release-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, 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 post-marketing 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-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 coadministration of CYP2D6 inhibitors which may increase the risk with increased exposure to dextroamphetamine sulfate extended-release. 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 with MAOI drugs is contraindicated *[see Contraindications].*

Discontinue treatment with dextroamphetamine sulfate extended-release and any concomitant serotonergic agents immediately if the above symptoms occur, and initiate supportive symptomatic treatment. If concomitant use of dextroamphetamine sulfate extended-release with other serotonergic drugs or CYP2D6 inhibitors is clinically warranted, initiate dextroamphetamine sulfate extended-release 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 1 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, 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 in a safe place, preferably locked, and instruct patients to not give dextroamphetamine

sulfate extended-release 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 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 can elevate blood pressure and heart rate *[see Warnings]*.

Psychiatric Adverse Reactions

Advise patients that dextroamphetamine sulfate extended-release, 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 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 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.
- 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. 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. Coadministration of dextroamphetamine sulfate extended-release 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 and CYP2D6 inhibitors may increase the exposure of dextroamphetamine sulfate extended-release 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 initiation and after a dosage increase. If serotonin syndrome occurs, discontinue dextroamphetamine sulfate extended-release 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 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 initiation or dosage increase. If serotonin syndrome occurs, discontinue dextroamphetamine sulfate extended-release 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 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; 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.

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 have not been performed.

Pregnancy

Teratogenic Effects

Dextroamphetamine sulfate extended-release has 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 1 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 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 is 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 EVENTS, contact Teva at 1-888-838-2872 or FDA at 1-800-FDA-1088 or http://www.fda.gov/medwatch.

DRUG ABUSE AND DEPENDENCE

Controlled Substance

Dextroamphetamine sulfate is a Schedule II controlled substance.

Abuse

Dextroamphetamine sulfate has a high potential for abuse and misuse which can lead to the development of a substance use disorder, including addiction *[see Warnings]*. Dextroamphetamine 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 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, 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 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 include dysphoric mood; depression; fatigue; vivid, unpleasant dreams; insomnia or hypersomnia; increased appetite; and psychomotor retardation or agitation.

Tolerance

Dextroamphetamine 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. The pharmacokinetic profile of

Dextroamphetamine sulfate 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 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 extended-release 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.

Extended-release capsules may be used for once-a-day dosage wherever appropriate.

Attention Deficit Disorder with Hyperactivity

The 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. Extended-release capsules may be used for once-a-day dosage wherever appropriate.

HOW SUPPLIED

Dextroamphetamine Sulfate Extended-Release Capsules are available as follows:

5 mg - Capsules with a light brown opaque cap and body are printed with  and 0303 on both cap and body in black ink and contain 5 mg of dextroamphetamine sulfate, USP. Capsules are supplied in bottles of 90 (NDC 45963-303-09).

10 mg - Capsules with a light brown opaque cap and light orange transparent body are printed with  and 0304 on both cap and body in black ink and contain 10 mg of

dextroamphetamine sulfate, USP. Capsules are supplied in bottles of 90 (NDC 45963-304-09).

15 mg - Capsules with a light brown opaque cap and light orange transparent body are printed with  and 0305 on both cap and body in black ink and contain 15 mg of dextroamphetamine sulfate, USP. Capsules are supplied in bottles of 90 (NDC 45963-305-09).

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

Dispense in a tight, light-resistant container as defined in the USP.

Dispense with Medication Guide available at: www.tevausa.com/medguides

Manufactured For:

Teva Pharmaceuticals

Parsippany, NJ 07054

Rev. E 9/2024

MEDICATION GUIDE

Dispense with Medication Guide available at: www.tevausa.com/medguides

MEDICATION GUIDE
Dextroamphetamine Sulfate (dex'' troe am fet' a meen sul' fate)
Extended-Release Capsules, CII

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 has 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 it is 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 is safe and effective in children under 6 years of age.

Dextroamphetamine sulfate extended-release capsules are a federally controlled substance (CII) because it contains 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 it from theft. Never give your dextroamphetamine sulfate extended-release capsules to anyone else because it 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 passes 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 is an extended-release capsule. It releases medicine into your body throughout the day.

If you or your child take too much Dextroamphetamine sulfate extended-release capsules, call your healthcare provider or Poison Help line at 1800-222-1222 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 is 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 it was 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

Inactive ingredients: denatured alcohol, ammonium hydroxide, ethylcellulose, gelatin, hydroxypropyl cellulose, hypromellose, medium chain triglycerides, oleic acid, polyethylene glycol and sugar spheres (which contain sucrose and corn starch).

The capsule shells of the 5 mg, 10 mg and 15 mg contain black iron oxide, red iron oxide, silicon dioxide, sodium lauryl sulfate, talc, titanium dioxide and yellow iron oxide. In addition, the 10 mg and 15 mg capsule shell contains FD&C Red #40 and D&C Yellow #10.

The capsule shells are imprinted with black ink which contains: ammonium hydroxide, black iron oxide, butyl alcohol, dehydrated alcohol, isopropyl alcohol, potassium hydroxide, propylene glycol, purified water, shellac, and strong ammonia solution.

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

Manufactured For:

Teva Pharmaceuticals

Parsippany, NJ 07054

For more information about Dextroamphetamine sulfate extended-release capsules, call Teva at 1-888-838-2872.

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

Rev. E 9/2024

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 45963-303-09

Dextroamphetamine Sulfate Extended-Release Capsules 5 mg CII

PHARMACIST: Dispense the accompanying Medication Guide to each patient.

Rx only

90 Capsules

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 45963-304-09

Dextroamphetamine Sulfate Extended-Release Capsules 10 mg CII

PHARMACIST: Dispense the accompanying Medication Guide to each patient.

Rx only

90 Capsules

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 45963-305-09

Dextroamphetamine Sulfate Extended-Release Capsules 15 mg CII

PHARMACIST: Dispense the accompanying Medication Guide to each patient.

Rx only

90 Capsules

DEXTROAMPHETAMINE SULFATE

dextroamphetamine sulfate capsule, extended release

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:45963-303
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**
ALCOHOL (UNII: 3K9958V90M)	
AMMONIA (UNII: 5138Q19F1X)	
ETHYLCELLULOSE, UNSPECIFIED (UNII: 7Z8S9VYZ4B)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
OLEIC ACID (UNII: 2UMI9U37CP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYETHYLENE GLYCOL 8000 (UNII: Q662QK8M3B)	
SUCROSE (UNII: C151H8M554)	
STARCH, CORN (UNII: O8232NY3SJ)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SHELLAC (UNII: 46N107B71O)	

Product Characteristics

Color	brown (light)	**Score**	no score
Shape	CAPSULE	**Size**	14mm
Flavor		**Imprint Code**	0303
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45963-303-09	90 in 1 BOTTLE; Type 0: Not a Combination Product	06/19/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA203901	06/19/2014	

DEXTROAMPHETAMINE SULFATE

dextroamphetamine sulfate capsule, extended release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:45963-304
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
ALCOHOL (UNII: 3K9958V90M)	
AMMONIA (UNII: 5138Q19F1X)	
ETHYLCELLULOSE, UNSPECIFIED (UNII: 7Z8S9VYZ4B)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
HYDROXYPROPYL CELLULOSE (90000 WAMW) (UNII: UKE75GEA7F)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
OLEIC ACID (UNII: 2UMI9U37CP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYETHYLENE GLYCOL 8000 (UNII: Q662QK8M3B)	
SUCROSE (UNII: C151H8M554)	
STARCH, CORN (UNII: O8232NY3SJ)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SHELLAC (UNII: 46N107B71O)	

Product Characteristics

Color	orange (light) , brown (light)	**Score**	no score
Shape	CAPSULE	**Size**	14mm
Flavor		**Imprint Code**	0304
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45963-304-09	90 in 1 BOTTLE; Type 0: Not a Combination Product	06/19/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA203901	06/19/2014	

DEXTROAMPHETAMINE SULFATE

dextroamphetamine sulfate capsule, extended release

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:45963-305
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**
ALCOHOL (UNII: 3K9958V90M)	
AMMONIA (UNII: 5138Q19F1X)	
ETHYLCELLULOSE, UNSPECIFIED (UNII: 7Z8S9VYZ4B)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
OLEIC ACID (UNII: 2UMI9U37CP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYETHYLENE GLYCOL 8000 (UNII: Q662QK8M3B)	
SUCROSE (UNII: C151H8M554)	
STARCH, CORN (UNII: O8232NY3SJ)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SHELLAC (UNII: 46N107B71O)	

Product Characteristics

Color	orange (light) , brown (light)	**Score**	no score
Shape	CAPSULE	**Size**	16mm
Flavor		**Imprint Code**	0305
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45963-305-09	90 in 1 BOTTLE; Type 0: Not a Combination Product	06/19/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA203901	06/19/2014	

Labeler - Actavis Pharma, Inc. (119723554)

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