AMPHETAMINE SULFATE- amphetamine sulfate tablet
Bryant Ranch Prepack

AMPHETAMINE SULFATE TABLETS, USP, CII

WARNING

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

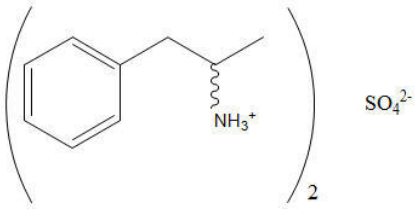
MISUSE OF AMPHETAMINE MAY CAUSE SUDDEN DEATH AND SERIOUS CARDIOVASCULAR ADVERSE EVENTS.

DESCRIPTION

Amphetamine Sulfate is a sympathomimetic amino of the amphetamine group. It is a white, odorless crystalline powder. It has a slightly bitter taste. Its solutions are acid to litmus, having a pH of 5.0 to 6.0. It is freely soluble in water and slightly soluble in alcohol.

Each tablet, for oral administration contains 5 mg or 10 mg of amphetamine sulfate. Each tablet also contains the following inactive ingredients: crospovidone, silicified microcrystalline cellulose and stearic acid. The 10 mg tablet also contains FD&C Blue #1.

Structural Formula:



$C_{18}H_{28}N_2SO_4$ **MW 368.49**

CLINICAL PHARMACOLOGY

Amphetamines are non-catecholamine, sympathomimetic amines with CNS stimulant activity. Peripheral actions include elevations of systolic and diastolic blood pressures, and weak bronchodilator, and respiratory stimulant action.

Amphetamine, as the racemic form, differs from dextroamphetamine in a number of ways. The l-isomer is more potent than the d-isomer in cardiovascular activity, but much less potent in causing CNS excitatory effects. The racemic mixture also is less effective as an appetite suppressant when compared to dextroamphetamine. There is neither

specific evidence which clearly establishes the mechanism whereby amphetamines produce mental and behavioral effects in children, nor conclusive evidence regarding how those effects relate to the condition of the central nervous system.

Drugs in this class used in obesity are commonly known as "anorectics" or "anorexigenics." It has not been established, however, that the action of such drugs in treating obesity is primarily one of appetite suppression. Other central nervous system actions or metabolic effects, may be involved, for example. Adult obese subjects instructed in dietary management and treated with "anorectic" drugs lose more weight on the average than these treated with placebo and diet, as determined in relatively short- term clinical trials.

The magnitude of increased weight loss of drug-treated patients over placebo-treated patients is only a fraction of a pound a week. The rate of weight loss is greatest in the first weeks of therapy for both drug and placebo subjects and tends to decrease in succeeding weeks. The origins of the increased weight loss due to the various possible drug effects are not established. The amount of weight loss associated with the use of an "anorectic" drug varies from trial to trial, and the increased weight loss appears to be related in part to variables other than the drug prescribed, such as the physician-investigator, the population treated, and the diet prescribed. Studies do not permit conclusions as to the relative importance of the drug and nondrug factors on weight loss.

The natural history of obesity is measured in years, whereas the studies cited are restricted to few weeks duration; thus, the total impact of drug-induced weight loss over that of diet alone must be considered clinically limited.

INDICATIONS AND USAGE

Amphetamine Sulfate Tablets, USP, are indicated for:

1. **Narcolepsy**
2. **Attention Deficit Disorder with Hyperactivity** as an integral part of a total treatment program which typically includes other remedial measures (psychological, educational, social) for a stabilizing effect in children with behavioral syndrome characterized by the following group of developmentally inappropriate symptoms: moderate to severe distractibility, short attention span, hyperactivity, emotional lability, and impulsivity. The diagnosis of the syndrome should not be made with finality when these symptoms are only of comparatively recent origin. Nonlocalizing (soft) neurological signs, learning disability, and abnormal EEG may or may not be present, and a diagnosis of central nervous system dysfunction may or not be warranted.
3. **Exogenous Obesity** as a short term (a few weeks) adjunct in a regimen of weight reduction based on caloric restriction for patients refractory to alternative therapy, e.g., repeated diets, group programs, and other drugs. The limited usefulness of amphetamines (see CLINICAL PHARMACOLOGY) should be weighed against possible risks inherent in use of the drug, such as those described below.

CONTRAINDICATIONS

Advanced arteriosclerosis, symptomatic cardiovascular disease, moderate to severe

hypertension, hyperthyroidism, known hypersensitivity or idiosyncrasy to the sympathomimetic amines.

Agitated states.

Patients with a history of drug abuse.

During or within 14 days following the administration of monoamine oxidase inhibitors (hypertensive crises may result).

WARNING

Serious Cardiovascular Events

Sudden Death and Pre-Existing Structural Cardiac Abnormalities or Other Serious Heart Problems

Children and Adolescents

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

Adults

Sudden deaths, stroke, and myocardial infarction have been reported in adults taking stimulant drugs at usual doses for ADHD. Although the role of stimulants in these adult cases is also unknown, adults have a greater likelihood than children of having serious structural cardiac abnormalities, cardiomyopathy, serious heart rhythm abnormalities, coronary artery disease, or other serious cardiac problems. Adults with such abnormalities should also generally not be treated with stimulant drugs (see CONTRAINDICATIONS).

Hypertension and other Cardiovascular Conditions

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

Assessing Cardiovascular Status in Patients being Treated with Stimulant Medications

Children, adolescents, or adults who are being considered for treatment with stimulant

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

Psychiatric Adverse Events

Pre-Existing Psychosis

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

Bipolar Illness

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

Emergence of New Psychotic or Manic Symptoms

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

Aggression

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

Long-Term Suppression of Growth

Careful follow-up of weight and height in children ages 7 to 10 years who were randomized to either methylphenidate or non-medication treatment groups over 14 months, as well as in naturalistic subgroups of newly methylphenidate-treated and non-medication treated children over 36 months (to the ages of 10 to 13 years), suggests that consistently medicated children (i.e., treatment for 7 days per week throughout the year) have a temporary slowing in growth rate (on average, a total of about 2 cm less growth in height and 2.7 kg less growth in weight over 3 years), without evidence of

growth rebound during this period of development. Published data are inadequate to determine whether chronic use of amphetamines may cause a similar suppression of growth, however, it is anticipated that they likely have this effect as well. Therefore, growth should be monitored during treatment with stimulants, and patients who are not growing or gaining height or weight as expected may need to have their treatment interrupted.

Seizures

There is some clinical evidence that stimulants may lower the convulsive threshold in patients with prior history of 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 Amphetamine Sulfate Tablets, used to treat ADHD are associated with peripheral vasculopathy, including Raynaud's phenomenon. Signs and symptoms are usually intermittent and mild; however, very rare sequelae include digital ulceration and/or soft tissue breakdown. Effects of peripheral vasculopathy, including Raynaud's phenomenon, were observed in post-marketing reports at different times and at therapeutic doses in all age groups throughout the course of treatment. Signs and symptoms generally improve after reduction in dose or discontinuation of drug. Careful observation for digital changes is necessary during treatment with ADHD stimulants. Further clinical evaluation (e.g., rheumatology referral) may be appropriate for certain patients.

Serotonin Syndrome

Serotonin syndrome, a potentially life-threatening reaction, may occur when amphetamines are used in combination with other drugs that affect the serotonergic neurotransmitter 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 Amphetamine Sulfate Tablets. 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 Amphetamine Sulfate Tablets with MAOI drugs is contraindicated (see CONTRAINDICATIONS).

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

Visual Disturbance

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

PRECAUTIONS

General

Caution is to be exercised in prescribing amphetamines for patients with even mild hypertension.

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

Information for Patients

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

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

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

Drug Interactions

Acidifying agents

Gastrointestinal acidifying agents (guanethidine, reserpine, glutamic acid HCl, ascorbic acid, fruit juices, etc.) lower absorption of amphetamines. Urinary acidifying agents (ammonium chloride, sodium acid phosphate, etc.) increase concentration of the ionized species of the amphetamine molecule, thereby increasing urinary excretion. Both groups of agents lower blood levels and efficacy of amphetamines.

Adrenergic blockers

Adrenergic blockers are inhibited by amphetamines.

Alkalinizing agents

Gastrointestinal alkalinizing agents (sodium bicarbonate, etc.) increase absorption of amphetamines. Urinary alkalinizing agents (acetazolamide, some thiazides) increase the concentration of the non-ionized species of the amphetamine molecule, thereby decreasing urinary excretion. Both groups of agents increase blood levels and therefore potentiate the action of amphetamines.

Antidepressants tricyclic

Amphetamines may enhance the activity of tricyclic or sympathomimetic agents; d-amphetamine with desipramine or protriptyline and possibly other tricyclics cause striking and sustained increases in the concentration of d- amphetamine in the brain; cardiovascular effects can be potentiated.

CYP2D6 Inhibitors

The concomitant use of Amphetamine Sulfate Tablets and CYP2D6 inhibitors may increase the exposure of Amphetamine Sulfate Tablets compared to the use of the drug alone and increase the risk of serotonin syndrome. Initiate with lower doses and monitor patients for signs and symptoms of serotonin syndrome particularly during Amphetamine Sulfate Tablets initiation and after a dosage increase. If serotonin syndrome occurs, discontinue Amphetamine Sulfate Tablets and the CYP2D6 inhibitor (see WARNING, OVERDOSAGE). Examples of CYP2D6 Inhibitors include paroxetine and fluoxetine (also serotonergic drugs), quinidine, ritonavir.

Serotonergic Drugs

The concomitant use of Amphetamine Sulfate Tablets and serotonergic drugs increases the risk of serotonin syndrome. Initiate with lower doses and monitor patients for signs and symptoms of serotonin syndrome, particularly during Amphetamine Sulfate Tablets initiation or dosage increase. If serotonin syndrome occurs, discontinue Amphetamine Sulfate Tablets and the concomitant serotonergic drug(s) (see WARNING 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

MAOI antidepressants, as well as a metabolic of furazolidone, slow amphetamine metabolism. This slowing potentiates amphetamines, increasing their affect on the release of norepinephrine and other monoamines from adrenergic nerve endings; this can cause headaches and other signs of hypertensive crisis. A variety of neurological toxic effects and malignant hyperpyrexia can occur, sometimes with fatal results.

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 amphetamine, 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 affects of amphetamines.

Lithium carbonate

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

Meperidine

Amphetamines potentiate the analgesic effect of meperidine.

Methenamine therapy

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

Norepinephrine

Amphetamines enhance the adrenergic effect of norepinephrine.

Phenobarbital

Amphetamines may delay intestinal absorption of Phenobarbital. 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 amphetamine sulfate have not been performed.

Pregnancy

Teratogenic Effects

Dextroamphetamine sulfate 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. There are no adequate and well-controlled studies in pregnant women. Amphetamine Sulfate Tablets 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 children have not been well established.

Amphetamines are not recommended for use as anorectic agents in children under 12 years of age, or in children under 3 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 is 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/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 phonic 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 when amphetamines are used for other than the anorectic effect.

Allergic

Urticaria

Endocrine

Impotence, changes in libido, and frequent or prolonged erections.

Musculoskeletal

Rhabdomyolysis

DRUG ABUSE AND DEPENDENCE

Amphetamine Sulfate Tablets are a Schedule II controlled substance. Amphetamines have been extensively abused. Tolerance, extreme psychological dependence, and severe social disability have occurred. There are reports of patients who have increased the dosage to many times the recommended. Abrupt cessation following prolonged high dosage administration results in extreme fatigue and mental depression; changes are also noted on the sleep EEG. Manifestations of chronic intoxication with amphetamines include severe dermatosis, marked insomnia, irritability, hyperactivity and personality changes. The most severe manifestation of chronic intoxication is psychosis, often clinically indistinguishable from schizophrenia. This is rare with oral amphetamines.

OVERDOSAGE

Individual patient response to amphetamines varies widely. While toxic symptoms occasionally occur as an idiosyncrasy at doses as low as 2 mg, they are rare with doses

of less than 15 mg; 30 mg can produce severe reactions, yet doses of 400 to 500 mg are not necessarily fatal.

In rats, the oral LD_{50} of dextroamphetamine sulfate is 96.8 mg/Kg.

Symptoms

Manifestations of acute overdosage with amphetamines include restlessness, tremor, hyperreflexia, rhabdomyolysis, rapid respiration, hyperpyrexia, confusion, assaultiveness, hallucinations, panic states. Fatigue and depression usually follow the central stimulation. Cardiovascular effects include arrhythmias, hypertension, or hypotension and circulatory collapse. Gastrointestinal symptoms include nausea, vomiting, diarrhea, and abdominal cramps. Fatal poisoning is usually preceded by convulsions and coma.

Treatment

Management of acute amphetamine intoxication is largely symptomatic and includes gastric lavage and sedation with a barbiturate. Experience with hemodialysis or peritoneal dialysis is inadequate to permit recommendation in this regard. Acidification of the urine increases amphetamine excretion. If acute, severe hypertension complicates amphetamine overdosage, administration of intravenous phentolamine has been suggested. However, a gradual drop in blood pressure will usually result when sufficient sedation has been achieved. Chlorpromazine antagonizes the central stimulant effects of amphetamines and can be used to treat amphetamine intoxication.

DOSAGE AND ADMINISTRATION

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

Narcolepsy

Usual dose is 5 to 60 milligrams 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, Amphetamine Sulfate Tablets may be used. The suggested initial dose for patients aged 6 to 12 is 5 mg daily; daily dose may be raised in increments of 5 mg at weekly intervals until optimal response obtained. In patients 12 years of age and older, start with 10 mg daily; daily dosage may be raised in increments of 10 mg at weekly intervals until optimal response is obtained. If bothersome adverse reactions appear (e.g., insomnia or anorexia) dosage should be reduced. Give the first dose on awakening; additional doses (5 or 10 mg) at intervals of 4 to 6 hours.

Attention Deficit Disorder with Hyperactivity

Not recommended for children under 3 years of age.

In children from 3 to 5 years of age, start with 2.5 mg daily; daily dosage may be raised in increments of 2.5 mg at weekly intervals until optimal response is obtained.

In children 6 years of age or 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 milligrams per day.

With tablets give first dose on awakening; additional doses (1 to 2) at intervals of 4 to 6 hours.

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

Exogenous Obesity

Usual dosage is up to 30 mg daily, taken in divided doses of 5 to 10 mg, 30 to 60 minutes before meals. Not recommended for this use in children under 12 years of age.

HOW SUPPLIED

Amphetamine Sulfate Tablets, USP, are supplied as follows:

10 mg: Blue, round tablet, debossed "EVK" on one side, and "10" with double scores on the other side in:

Bottles of 100 tablets, NDC 63629-2498-1

Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature.]
Dispense in a well-closed container, as defined in the USP.

Repackaged/Relabeled by:
Bryant Ranch Prepack, Inc.
Burbank, CA 91504

Manufactured for:
Wilshire Pharmaceuticals, Inc.
Atlanta, GA 30328
AMAG-PI-02

Rev. 02/22

MEDICATION GUIDE
Amphetamine Sulfate Tablets, USP

Read this Medication Guide before you or your child starts taking Amphetamine Sulfate Tablets and each time you get a refill. There may be new information. This information does not take the place of talking to your doctor about you or your child's treatment.

What is the most important information I should know about Amphetamine Sulfate Tablets?

Amphetamine Sulfate Tablets are a stimulant medicine. Some people have had the following problems when taking stimulant medicines such as Amphetamine Sulfate Tablets:

1. Heart-related problems:

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

- increased blood pressure and heart rate

Tell your doctor if you or your child has any heart problems, heart defects, high blood pressure, or a family history of these problems.
Your doctor should check you or your child carefully for heart problems before starting Amphetamine Sulfate Tablets.
Your doctor should check you or your child's blood pressure and heart rate regularly during treatment with Amphetamine Sulfate Tablets.
Call your doctor right away if you or your child have any signs of heart problems such as chest pain, shortness of breath, or fainting while taking Amphetamine Sulfate Tablets.
2. **Mental (Psychiatric) problems including:**
In children, teenagers, and adults:
- new or worse behavior and thought problems
- new or worse bipolar illness
- new or worse aggressive behavior or hostility

In Children and Teenagers who have psychiatric problems, new psychotic symptoms such as:
- hearing voices
- seeing things that are not real
- believing things that are not true
- being suspicious
- new manic symptoms

Tell your doctor about any mental problems you or your child have, or about a family history of suicide, bipolar illness, or depression.
Call your doctor right away if you or your child have any new or worsening mental symptoms or problems while taking Amphetamine Sulfate Tablets, especially:
- **seeing or hearing things that are not real**
- **believing things that are not real**
- **being suspicious**

3. Circulation problems in fingers and toes [Peripheral vasculopathy, including Raynaud's phenomenon].
- Fingers or toes may feel numb, cool, painful
- Fingers or toes may change color from pale, to blue, to red

Tell your doctor if you have or your child has numbness, pain, skin color change, or sensitivity to temperature in your fingers or toes.
Call your doctor right away if you have or your child has any signs of unexplained wounds appearing on fingers or toes while taking Amphetamine Sulfate Tablets.

What are Amphetamine Sulfate Tablets?
- Amphetamine Sulfate Tablets are a central nervous system stimulant prescription medicine used for the treatment of:

- **a sleep disorder called narcolepsy.**
- **Attention-Deficit Hyperactivity Disorder (ADHD).** Amphetamine Sulfate Tablets may help increase attention and decrease impulsiveness and hyperactivity in patients with ADHD. Amphetamine Sulfate Tablets should be used as part of a total treatment program for ADHD that may include counseling or other therapies.
- **exogenous obesity.** Amphetamine Sulfate Tablets may be used as part of a short-term, weight reduction program for obesity.

- Amphetamine Sulfate Tablets are not for use as an anorectic agent for exogenous obesity in children less than 12 years of age.
- Amphetamine Sulfate Tablets are not for use for ADHD in children less than 3 years old.
- The effects of long term use of Amphetamine Sulfate Tablets in children are not known.

Amphetamine Sulfate Tablets are a federally controlled substance (CII) because they contain amphetamine that can be a target for people who abuse prescription medicines or street drugs. Keep Amphetamine Sulfate Tablets in a safe place to protect them from theft. Never give your Amphetamine Sulfate Tablets to anyone else, because they may cause death or harm them. Selling or giving away Amphetamine Sulfate Tablets is against the law.

Tell your doctor if you or your child has (or has a family history of) ever abused or been dependent on alcohol, prescription medicines or street drugs.

Who should not take Amphetamine Sulfate Tablets?

Do not take Amphetamine Sulfate Tablets if you or your child:

- have heart problems or hardening of the arteries
- have moderate to severe high blood pressure
- have hyperthyroidism
- are very anxious, tense, or agitated
- have a history of drug abuse
- are taking or have taken within the past 14 days an anti-depression medicine called a monoamine oxidase inhibitor or MAOI
- are sensitive to, allergic to, or had a reaction to other stimulant medicines

What should I tell my doctor before taking Amphetamine Sulfate Tablets?

Before you or your child takes Amphetamine Sulfate Tablets, tell your doctor if you or your child has or if there is a family history of:

- heart problems, heart defects, high blood pressure
- mental problems including psychosis, mania, bipolar illness, or depression
- tics or Tourette's syndrome
- thyroid problems
- seizures or have had an abnormal brain wave test (EEG)
- circulation problems in fingers and toes

Tell your doctor if:

- you or your child are pregnant or planning to become pregnant. It is not known if Amphetamine Sulfate Tablets will harm your unborn baby.
- you or your child are breastfeeding or plan to breastfeed. Amphetamine Sulfate Tablets can pass into your milk and may harm your baby. Talk to your doctor about the best way to feed your baby if you take Amphetamine Sulfate Tablets. Do not breastfeed while taking Amphetamine Sulfate Tablets.

Tell your doctor about all the medicines that you or your child takes, including prescription and nonprescription medicines, vitamins, and herbal supplements.

Amphetamine Sulfate Tablets and some medicines may interact with each other and cause serious side effects. Sometimes the doses of other medicines will need to be adjusted while taking Amphetamine Sulfate Tablets.

Your doctor will decide whether Amphetamine Sulfate Tablets can be taken with other medicines.

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

Know the medicines that you or your child takes.

Keep a list of your medicines with you to show your doctor and pharmacist when you get a new medicine.

Do not start any new medicine while taking Amphetamine Sulfate Tablets without talking to your doctor first.

How should I take Amphetamine Sulfate Tablets?
- Take Amphetamine Sulfate Tablets exactly as your doctor tells you to take it.
- Your doctor may change the dose until it is right for you or your child.
- The first dose of the day is usually taken when you first wake in the morning.
- Amphetamine Sulfate Tablets may cause problems sleeping if taken late at night.
- Amphetamine Sulfate Tablets can be taken with or without food.
- From time to time, your doctor may stop Amphetamine Sulfate Tablets treatment for a while to check ADHD symptoms.
- Your doctor may do regular checks of the blood, heart, and blood pressure while taking Amphetamine Sulfate Tablets.
- Children should have their height and weight checked often while taking Amphetamine Sulfate Tablets. Amphetamine Sulfate Tablets treatment may be stopped if a problem is found during these check-ups.
- If you or your child takes too many Amphetamine Sulfate Tablets, call your doctor right away, or go to the nearest hospital emergency room.

What should I avoid while taking Amphetamine Sulfate Tablets?

Do not drive, operate machinery, or do other dangerous activities until you know how Amphetamine Sulfate Tablets affect you.

What are possible side effects of Amphetamine Sulfate Tablets?

Amphetamine Sulfate Tablets may cause serious side effects, including:

See **"What is the most important information I should know about Amphetamine Sulfate Tablets?"** for information on reported heart and mental problems.

Other serious side effects include:

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

The most common side effects of Amphetamine Sulfate Tablets include:

- headache
- stomach ache
- trouble sleeping
- decreased appetite
- unpleasant taste
- nervousness
- dizziness
- sexual problems (impotence in males)
- vomiting
- itching
- diarrhea or constipation
- dry mouth
- weight loss
- mood swings

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

These are not all the possible side effects of Amphetamine Sulfate Tablets. For more information ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to

Wilshire Pharmaceuticals, Inc., Medical Information at 1-877-495-6856 or FDA at 1-800-FDA-1088.

How should I store Amphetamine Sulfate Tablets?

- Store Amphetamine Sulfate Tablets at room temperature between 68˚F to 77˚F (20˚C to 25˚C).
- Keep Amphetamine Sulfate Tablets and all medicines out of the reach of children.

General information about the safe and effective use of Amphetamine Sulfate Tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Amphetamine Sulfate Tablets for a condition for which they were not prescribed. Do not give Amphetamine Sulfate Tablets to other people, even if they have the same condition. It may harm them and it is against the law.

This Medication Guide summarizes the most important information about Amphetamine Sulfate Tablets. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about Amphetamine Sulfate Tablets that was written for healthcare professionals.

For more information about Amphetamine Sulfate Tablets, please contact Wilshire Pharmaceuticals, Inc. at 1-877-495-6856.

What are the ingredients in Amphetamine Sulfate Tablets?

Active Ingredient: amphetamine sulfate

Inactive Ingredients: crospovidone, silicified microcrystalline cellulose, and stearic acid. The 10 mg tablets also contain FD&C Blue #1.

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

Manufactured for:
Wilshire Pharmaceuticals, Inc.
Atlanta, GA 30328
AMAG-MG-01

Rev. 11/19

Amphetamine Sulfate (CII) 10 mg Tab, #100

Each tablet contains: 10 mg Amphetamine Sulfate, USP. Keep this and all medications out of the reach of children. Tamper evident by foil seal under cap. Do not use if the seal is broken.

Usual Dose: Scan Package Insert QR Code. Pharmacist: Dispense the Medication Guide to each patient.

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. Do not use if seal is broken.

Package Insert

Dispense in a well-closed container as defined in the USP.

NDC 63629-2498-1

Amphetamine Sulfate Tablets, USP

10 mg

Rx only

100 Tablets

BRP PHARMACEUTICALS

Relabeled by:
Bryant Ranch Prepack, Inc.
Burbank, CA 91504 USA

Manufactured by:
Wilshire Pharmaceuticals, Inc.

AMPHETAMINE SULFATE

amphetamine sulfate tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:63629-2498(NDC:52536-059)
Route of Administration	ORAL	**DEA Schedule**	CII

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AMPHETAMINE SULFATE (UNII: 6DPV8NK46S) (AMPHETAMINE - UNII:CK833KGX7E)	AMPHETAMINE SULFATE	10 mg

Inactive Ingredients

Ingredient Name	Strength
CROSPOVIDONE (UNII: 2S7830E561)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Product Characteristics

Color	BLUE	**Score**	4 pieces
Shape	ROUND	**Size**	8mm
Flavor		**Imprint Code**	EVK;10
Contains			

Packaging

#	Item Code	Package Description	Marketing Start	Marketing End

#	Item Code	Package Description	Date	Date
1	NDC:63629-2498-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/29/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA200166	03/29/2018	

Labeler - Bryant Ranch Prepack (171714327)

Registrant - Bryant Ranch Prepack (171714327)

Establishment

Name	Address	ID/FEI	Business Operations
Bryant Ranch Prepack		171714327	REPACK(63629-2498) , RELABEL(63629-2498)

Revised: 8/2025 Bryant Ranch Prepack