

PRESCRIBING INFORMATION

 **DEXEDRINE[®]**

(dextroamphetamine sulfate)

5 mg Tablets

10 mg and 15 mg Spansules[®]

Sympathomimetic

Paladin Labs Inc.
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PRESCRIBING INFORMATION

NAME OF DRUG

 **DEXEDRINE®**

(dextroamphetamine sulfate)

5 mg Tablets

10 mg and 15 mg Spansules

THERAPEUTIC CLASSIFICATION

Sympathomimetic

ACTIONS

Dextroamphetamine (dexamphetamine, d-amphetamine) sulfate is a sympathomimetic agent with indirect effects on adrenergic receptors. It has alpha- and beta-adrenergic activity. It has actions qualitatively similar to those of amphetamine sulfate but is approximately twice as potent. It has a marked stimulant effect on the central nervous system, particularly the cerebral cortex and the respiratory and vasomotor centres.

Dextroamphetamine sulfate causes a lessening of fatigue, an increase in mental activity, an elevation of mood, and a general feeling of well-being. However, its indiscriminate use in attempts to increase capacity for work or to overcome fatigue is undesirable. At high doses, it produces a euphoria, which upon abrupt withdrawal of the drug reverts to severe depression and lethargy.

The mechanism by which amphetamines produce mental and behavioural effects in children is not conclusively established.

INDICATIONS AND CLINICAL USE

DEXEDRINE[®] (dextroamphetamine sulfate) is indicated in the adjunctive treatment of:

- Narcolepsy

Attention Deficit Hyperactivity Disorder (ADHD)

A diagnosis of ADHD (DSM-IV) implies the presence of hyperactive-impulsive or inattentive symptoms that caused impairment and that were present before age 7 years. The symptoms must be persistent, must be more severe than is typically observed in individuals at a comparable level of development, must cause clinically significant impairment, e.g., in social, academic, or occupational functioning, and must 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. For a Combined Type diagnosis, both inattentive and hyperactive-impulsive criteria must be met.

Special Diagnostic Considerations

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

Need for Comprehensive Treatment Program

DEXEDRINE[®] 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. Drug treatment is not intended for use in the patient who exhibits symptoms secondary to environmental factors and/or other primary psychiatric disorders, including psychosis. Appropriate educational placement is essential in children and adolescents with this diagnosis and psychosocial intervention is often helpful. When remedial measures alone are insufficient, the decision to prescribe drug treatment medication will depend upon the physician's assessment of the chronicity and severity of the patient's symptoms.

CONTRAINDICATIONS

- Advanced arteriosclerosis
- Symptomatic cardiovascular disease
- Moderate to severe hypertension
- Hyperthyroidism
- Hypersensitivity or idiosyncrasy to sympathomimetic amines
- Agitated state
- History of drug abuse
- Glaucoma
- Anxiety
- Tension
- Patients with known hypersensitivity to DEXEDRINE[®] or to any ingredient in the formulation or component of the container.
- Patients with motor tics or with a family history of diagnosis of Tourette's Syndrome (verbal tics).
- Concomitant treatment with MAO inhibitors.

During administration or within 14 days following the withdrawal of monoamine oxidase inhibitors, administration of DEXEDRINE[®] may cause hypertensive crises.

WARNINGS

Sudden Death and Pre-existing Structural Cardiac Abnormalities:

Children and Adolescents

Sudden death has been reported in association with stimulant drugs used for ADHD 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.

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).

General

Theoretically there exists a pharmacological potential for all ADHD drugs to increase the risk of sudden/cardiac death. Although confirmation of an incremental risk for adverse

cardiac events arising from treatment with ADHD medications is lacking, prescribers should consider this potential risk.

Hypertension and other Cardiovascular Conditions

Stimulant medications cause a modest increase in average blood pressure (about 2-4 mmHg) and average heart rate (about 3-6 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.

All drugs with sympathomimetic effects prescribed in the management of ADHD should be used with caution in patients who: a) are involved in strenuous exercise or activities b) use other stimulants or c) have a family history of sudden/cardiac death.

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.

Visual Disturbances

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

Amphetamines have been subject to extensive abuse. Tolerance, extreme psychological dependence, and severe social disability can occur. Patients have been reported to increase their dosage to many times the recommended level. The smallest possible amount of the drug should be prescribed or dispensed at one time.

PRECAUTIONS

Amphetamines may mask extreme fatigue, which can impair the ability to perform potentially hazardous activities such as operating machinery or driving motor vehicles; patients should be cautioned accordingly.

Amphetamines may alter insulin requirements in diabetes mellitus, and may decrease the hypotensive effect of guanethidine.

DEXEDRINE[®] tablets contain tartrazine (FD&C yellow #5) which can cause allergic type reactions (including bronchial asthma) in susceptible individuals, especially people with a history of allergy to aspirin. Cross-sensitivity to salicylates and tartrazine is frequently seen.

The possibility of tolerance and psychological dependence, particularly with excessive use, should be kept in mind. Therefore, care should be used in the selection of candidates for DEXEDRINE[®] therapy. Should psychological dependence occur, discontinue medication. Abrupt cessation following prolonged high dosage administration may result in extreme fatigue and mental depression. Changes have also been noted on the sleep EEG.

Manifestations of chronic intoxication with amphetamines include severe dermatoses, marked insomnia, irritability, hyperactivity, and personality changes. The most severe manifestation of chronic intoxication is psychosis, often clinically indistinguishable from schizophrenia.

Use in Children:

Amphetamines are not recommended for use in Attention-Deficit Hyperactivity Disorder in children under 6 years of age.

Long-term effects of amphetamines in children have not been well established.

Chronic administration of amphetamines may be associated with growth inhibition; growth should be monitored during treatment.

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

The presence of tics or Tourette's syndrome should be ruled out before administering amphetamines to children.

Drug Interactions:

Caution should be exercised when co-prescribing amphetamines and other drugs since clinically significant interactions with a number of drugs have been reported. In some instances, potentiation of CNS and cardiac effects could be life threatening. Dosages should be closely monitored.

Known interactions with amphetamines are as follows:

Synergistic interactions - tricyclic antidepressants, MAO inhibitors, meperidine, norepinephrine, phenobarbital, phenytoin, propoxyphene, acetazolamide, thiazides, gastrointestinal and urinary alkalinizing agents.

Antagonistic interactions - adrenergic blockers, antihistamines, antihypertensives, chlorpromazine, ethosuximide, guanethidine, haloperidol, lithium carbonate, methenamine, veratrum alkaloids, gastrointestinal and urinary acidifying agents.

Use in Pregnancy:

Safe use in pregnancy has not been established. 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 manifested by dysphoria, agitation and significant lassitude. Reproductive studies in mammals at high multiples of the human dose have suggested an embryotoxic and a teratogenic potential. Use of amphetamines by women who are or who may become pregnant, and especially those in the first trimester of pregnancy, requires that the potential benefit be weighed against the possible hazard to mother and child.

Nursing Mothers:

Amphetamines are excreted in human milk. Mothers taking DEXEDRINE[®] should be advised to refrain from nursing.

Laboratory Test Interactions:

Amphetamines can elevate plasma corticosteroid levels, particularly in the evening, and may interfere with urinary steroid determinations.

ADVERSE REACTIONS

Cardiovascular:

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

Central Nervous System:

Overstimulation, restlessness, dizziness, euphoria or dysphoria, dyskinesia, headache, insomnia, exacerbation of motor and phonic tics, Tourette's syndrome, tremor; rarely, psychotic episodes at recommended doses.

Gastrointestinal:

Dryness of the mouth, unpleasant taste, loss of appetite, diarrhea, constipation, other gastrointestinal disturbances, anorexia and weight loss.

Allergic:

Urticaria.

Other:

Impotence, changes in libido.

Post-marketing:

Sudden/Cardiac death.

SYMPTOMS AND TREATMENT OF OVERDOSE

The toxic dose of amphetamine varies widely according to the degree of tolerance present. Blood levels are, therefore, of little value in assessing the severity of the overdose; this assessment must depend almost entirely on clinical signs.

Symptoms:

Dilated and reactive pupils, shallow rapid respiration, rhabdomyolysis, hyperpyrexia, fever, chills, sweating, hyperactive tendon reflexes. Other symptoms are:

Central effects may include restlessness, tremor, aggressiveness, anxiety, confusion, delirium, hallucinations, panic attacks and even suicidal or homicidal tendencies. The stimulant effect is usually followed by depression, lethargy, exhaustion.

Cardiovascular effects may include anginal pain, extrasystoles and other arrhythmias, flushing, headache, hypertension or hypotension, pallor, palpitations, tachycardia. Circulatory collapse and syncope may occur.

Gastrointestinal effects include nausea, vomiting, diarrhea, abdominal cramps.

Fatal poisoning is usually preceded by convulsions and coma.

Treatment:

Treatment is essentially symptomatic and supportive. In addition to the usual measures (including emesis, gastric lavage, catharsis), sedatives should be given when indicated. Oral or parenteral barbiturates are generally used for this purpose. To provide a basal level of sedation, one or more doses of sodium amobarbital may be given by mouth or, if necessary, by intramuscular injection. This may be repeated as often as necessary and in quantities sufficient to control the symptoms.

Sedation may also be accomplished with chlorpromazine: in children 1 mg/kg body weight IM and in adults 100 mg IM, repeated at half-hourly intervals if necessary. If the amphetamine has been taken with a barbiturate, as is often the case, the chlorpromazine dosage should be halved.

Note: It has been stated that the effects of amphetamines are best treated with haloperidol (Med Lett 1983 Sep 16; 25:87), a dopamine antagonist with minimal anticholinergic side effects. Haloperidol, however, possesses central antiemetic properties; it may prolong the hypnotic action of barbiturates and may potentiate the effects of alcohol and other CNS depressant drugs; it may lower the convulsion threshold.

In general, the hypertension which may result from massive overdose of DEXEDRINE[®] does not require treatment. A gradual drop in blood pressure will usually result when sufficient sedation has been administered. Phentolamine may be used to decrease blood pressure and hyperthermia. In the presence of severe hypotension, the usual procedures employed for shock should be instituted.

Acidification of the urine enhances excretion. Experience with forced diuresis, hemodialysis, peritoneal dialysis or charcoal hemoperfusion is inadequate to permit recommendations in this regard.

Since much of the Spansule capsule medication is coated for gradual release, therapy directed at reversing the effects of the ingested drug and at supporting the patient should be continued for as long as overdosage symptoms remain. Saline cathartics are useful for hastening the evacuation of pellets that have not already released medication.

DOSAGE AND ADMINISTRATION

Dosing Considerations

DEXEDRINE[®] should be administered starting at the lowest possible dose. Dosage should then be individually and slowly adjusted, to the lowest effective dosage, since individual patient response to DEXEDRINE[®] varies widely. Time of administration should receive special attention - particularly with the Spansule capsule form - because of possible insomnia. Late evening medication should be avoided.

DEXEDRINE[®] should not be used in patients with symptomatic cardiovascular disease and should generally not be used in patients with known structural cardiac abnormalities (See **CONTRAINDICATIONS and WARNINGS**).

Theoretically there exists a pharmacological potential for all ADHD drugs to increase the risk of sudden/cardiac death. Although confirmation of an incremental risk for adverse cardiac events arising from treatment with ADHD medications is lacking, prescribers should consider this potential risk.

All drugs with sympathomimetic effects prescribed in the management of ADHD should be used with caution in patients who: a) are involved in strenuous exercise or activities b) use stimulants or c) have a family history of sudden/cardiac death. Prior to the initiation of treatments, a personal and family history should be obtained. In patients with relevant risk factors and based on the clinician's judgment, further cardiovascular evaluation may be considered.

Patients who are considered to need extended treatment with DEXEDRINE® should undergo periodic evaluation of their cardiovascular status. (see **WARNINGS**).

Narcolepsy:

Daily dosage may range from 5 mg to 60 mg depending on individual patient response.

Suggested initial dosage for patients aged 6 to 12; start with 5 mg daily; daily dosage may be raised in increments of 5 mg at weekly intervals until optimal response is obtained.

In patients 12 years of age and older: start with 10 mg daily; daily dosage may be raised in increments of 10 mg at weekly intervals until optimal response is obtained.

If bothersome adverse reactions appear (e.g., insomnia or anorexia), dosage should be reduced. Spansule capsules may be used for once-a-day dosage wherever appropriate. With tablets, give first dose on awakening; additional doses (1 or 2) at intervals of 4 to 6 hours.

Attention-deficit Hyperactivity Disorder in children:

Daily dosage may range from 2.5 mg to 40 mg, although some older children may require more than 40 mg daily for optimal response. If bothersome adverse reactions appear (e.g., insomnia or anorexia), dosage should be reduced. Spansule capsules may be used for once-a-day dosage wherever appropriate. With tablets, give first dose on awakening; additional doses (1 or 2) at intervals of 4 to 6 hours.

Not recommended for this use in children under 6 years of age.

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 mg per day.

Most children suffering from Attention-Deficit Hyperactivity Disorder require medication for several years, although once symptoms have been controlled, it may be possible to reduce dosage or to interrupt drug therapy during the summer months and at other times when the child is under less stress. During periods of interrupted drug therapy, behavioural symptoms should be assessed to determine whether their recurrence is sufficient to justify the resumption of treatment.

AVAILABILITY OF DOSAGE FORMS

DEXEDRINE® (dextroamphetamine sulfate) 5 mg Tablets:

Each orange, round-cornered, equilaterally triangular shaped, scored, compressed tablets, engraved "SKF E19" contain the medicinal ingredient dextroamphetamine sulfate (5 mg) and the following non-medicinal ingredients; calcium sulfate, gelatin, lactose, FD&C Yellow no. 6, FD&C Yellow no. 5, starch, stearic acid, sucrose and talc.

Available in bottles of 100 tablets.

DEXEDRINE® (dextroamphetamine sulfate) 10 mg and 15 mg Spansules:

Each sustained release capsule contains the medicinal ingredient dextroamphetamine sulfate (10 mg or 15 mg) and releases a therapeutic dose promptly with the remaining dose being delivered gradually without interruption to sustain the effects for 10 to 12 hours. The tapered-end capsules have a brown cap, a natural coloured body and contain two shades of orange pellets. Inactive ingredients consist of cetyl alcohol, D&C yellow no. 10, dibutyl sebacate, ethylcellulose, FD&C Blue No 1, FD&C Blue No. 1 aluminum lake, FD&C red no. 40, FD&C yellow no. 6, gelatin, hydroxypropyl methylcellulose, propylene glycol, povidone, silicon dioxide, sodium lauryl sulfate, sugar spheres and trace amounts of other inactive ingredients. The 10 mg Spansules (Size No. 4) are monogrammed "3513" on the cap with "10 mg" and "SB" on the body in white

ink. The 15 mg Spansules (Size No. 3) are monogrammed “3514” on the cap with “15 mg” and “SB” on the body in white ink.

Available in bottles of 100 capsules.

CONSUMER INFORMATION

DEXEDRINE® dextroamphetamine sulfate

This leaflet is published for DEXEDRINE®, approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about DEXEDRINE®. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

The following have been reported with use of DEXEDRINE® and other stimulant medicines.

1. Heart-related problems:

- sudden death in patients who have heart problems and heart defects
- stroke and heart attack in adults
- increased blood pressure and heart rate

Tell your doctor if you or your child have any heart problems, heart defects, high blood pressure, or a family history of these problems.

Your doctor may wish to check you or your child carefully for heart problems before starting DEXEDRINE®.

Your doctor may wish to check you or your child's blood pressure and heart rate regularly during treatment with DEXEDRINE®.

Call your doctor right away if you or your child has any signs of heart problems such as chest pain, shortness of breath, or fainting while taking DEXEDRINE®.

2. Mental (Psychiatric) problems:

All patients

- new or worse behaviour and thought problems
- new or worse bipolar illness
- new or worse aggressive behaviour or hostility

Children and Teenagers

- new psychotic symptoms (such as hearing voices, believing things that are not true, are suspicious) or new maniac 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 DEXEDRINE®, especially seeing or hearing things that are not real, believing things that are not real, or are suspicious.

What the medication is used for:

DEXEDRINE® (dextroamphetamine sulfate), a drug in the class of amphetamines (central nervous system stimulant), is used along with other therapies, for the treatment of:

- narcolepsy (a disorder that caused excessive sleepiness during the day and frequent and uncontrollable episodes of falling asleep).
- Attention-deficit Hyperactivity Disorder (ADHD) (a disorder characterized by a very short attention span, impulsiveness, and hyperactivity). DEXEDRINE® should be used as a part of a total treatment program for ADHD that may include counselling or other therapies.

What it does:

DEXEDRINE® causes a lessening of fatigue, an increase in mental activity, an elevation of mood, and a general feeling of well-being.

DEXEDRINE® helps increase attention (including the ability to follow directions and finish tasks) and decrease impulsiveness and hyperactivity in patients with ADHD.

When it should not be used:

You or your child should NOT take DEXEDRINE® if you or your child:

- have cardiovascular disease;
- have moderate to severe high blood pressure;
- have advanced arteriosclerosis (hardened arteries);
- have hyperthyroidism (an overactive thyroid gland);
- have allergies to DEXEDRINE® or to any ingredient in the formulation or component of the container;
- are sensitive to, allergic to, or had a reaction to other stimulant medicines or sympathomimetic amines;
- have glaucoma, an eye disease;
- have very anxious, tense, or agitated states;
- have motor tics (hard to control, repeat twitching of any parts of the body) or verbal tics (hard to control repeating of sounds or words) or Tourette's syndrome;
- have relatives with motor tics or verbal tics or Tourette's syndrome;
- had taken medications from the group called monoamine oxidase inhibitors (MAOI) within the last 14 days, as administration of DEXEDRINE® may cause hypertensive crises;
- have a history of drug abuse.

DEXEDRINE® is not recommended for use in children under 6 years of age.

Talk to your doctor if you believe any of these conditions apply to you or your child.

What the medicinal ingredient is:

DEXEDRINE[®] contains dextroamphetamine sulfate as the medicinal ingredient.

What the important nonmedicinal ingredients are:

DEXEDRINE[®] 5 mg tablets contain the following nonmedicinal ingredients: calcium sulfate, gelatin, lactose, FD&C Yellow no.6, FD&C Yellow no.5, starch, stearic acid, sucrose and talc.

DEXEDRINE[®] 10 mg and 15 mg spansules contain the following nonmedicinal ingredients: cetyl alcohol, D&C Yellow no. 10, dibutyl sebacate, ethylcellulose, FD&C Blue no. 1, FD&C Blue no. 1 aluminum lake, FD&C Red no. 40, FD&C Yellow no. 6, gelatin, hydroxypropyl methylcellulose, propylene glycol, povidone, silicon dioxide, sodium lauryl sulfate, and sugar spheres.

What dosage forms it comes in:

DEXEDRINE[®] is available as 5 mg tablets and 10 mg and 15 mg spansules.

WARNINGS AND PRECAUTIONS

Sudden death has been reported in association with stimulant drugs for ADHD treatment in children with structural heart abnormalities. DEXEDRINE[®] generally should not be used in children, adolescents or adults with known structural heart abnormalities.

Amphetamines may impair the ability to perform potentially hazardous activities such as operating machinery or driving.

BEFORE you use DEXEDRINE[®] talk to your doctor or pharmacist if you or your child:

- have mild high blood pressure;
- have a family history of sudden death or death related to heart problems;
- have heart disease or structural heart abnormalities;
- have mental problems including psychosis, mania, bipolar illness, depression, or a family history of suicide;
- have tics or Tourette's syndrome;
- have thyroid problems;
- have seizures or have had an abnormal brain wave test (EEG);
- do strenuous exercise;
- take other drugs for ADHD;
- have diabetes mellitus;
- have an allergy to tartazine (FD & C Yellow no. 5) or aspirin;

- is pregnant or plans to become pregnant;
- is breast feeding or plans to breastfeed;
- if you or your child have (or have a family history of) ever abused or been dependent on alcohol, prescription medicines or street drugs.

Amphetamines have been subject to extensive abuse. Tolerance, extreme psychological dependence, and severe social disability can occur. It is important that DEXEDRINE[®] be taken only as directed by your doctor.

INTERACTIONS WITH THIS MEDICATION

It is important to tell your doctor or pharmacist about all medicines that you or your child are taking including other medicines that a doctor has prescribed, medicines that you buy yourself without a prescription, and any herbal remedies that you or your child are taking, especially:

- anti-depression medicines including MAOIs
- blood pressure medicines
- antacids
- seizure medicines

While on DEXEDRINE[®] do not start taking a new medicine or herbal remedy before checking with your doctor.

PROPER USE OF THIS MEDICATION

Usual dose:

In order to receive the most benefit from DEXEDRINE[®], it is important that DEXEDRINE[®] be taken only as directed by your doctor. The doctor may adjust the amount of drug taken by your or your child until it is right for you or your child. From time to time, the doctor may interrupt treatment to check you or your child's symptoms while you or your child are not taking the drug.

Your doctor may do regular checks of the blood, heart, and blood pressure while taking DEXEDRINE[®]. Children should have their height and weight checked often while taking DEXEDRINE[®]. DEXEDRINE[®] treatment may be stopped if a problem is found during these check-ups.

Overdose:

Call the doctor **immediately** if you or your child takes more than the amount of DEXEDRINE[®] prescribed by the doctor.

Missed Dose:

If you forget to take your medicine, take it as soon as you remember. Then continue as before. Do not take a double dose to make up for forgotten individual doses.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Along with its desired effects, a medicine may cause some unwanted effects. Although not all of these side effects may occur, if they do occur, talk to your or your child's doctor.

Some of the side effects observed during treatment with stimulant medications such as DEXEDRINE[®] were slowing of growth (height and weight) in children, seizures (mainly in patients with a history of seizures), eye sight changes, tremors, headache, dizziness, loss of appetite, dry mouth, stomach upset, difficulty falling asleep, high blood pressure, irregular heartbeat, and irritability.

This is not a complete list of side effects. For any unexpected effects while taking DEXEDRINE[®], contact your doctor or pharmacist.

HOW TO STORE IT

DEXEDRINE[®] tablets and spansules should be stored at 15-30°C.

Do not take your medicine after the expiry date shown on the bottle.

As with all medicines keep out of the reach and sight of children.

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada collects information on serious and unexpected effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Health Canada by:

toll-free telephone: 866-234-2345

toll-free fax 866-678-6789

By email: cadrmpp@hc-sc.gc.ca

By regular mail:

National AR Centre

**Marketed Health Products Safety and Effectiveness
Information Division**

Marketed Health Products Directorate

Tunney's Pasture, AL 0701C

Ottawa ON K1A 0K9

NOTE: Before contacting Health Canada, you should contact your physician or pharmacist.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found by contacting the sponsor, Paladin Labs Inc.

6111 Royalmount Avenue, Suite 102

Montreal, Quebec

H4P 2T4

1-888-550-6060

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