DESCRIPTION

DESOXYN® (methamphetamine hydrochloride tablets, USP), chemically known as (S)-N,α-dimethylbenzeneethanamine hydrochloride, is a member of the amphetamine group of sympathomimetic amines. It has the following structural formula:

\[
\begin{align*}
\text{CH}_3 & - \text{CH} - \text{N} - \text{CH}_3 \\
\text{CH}_3 & \quad \text{Cl} \\
\end{align*}
\]

DESOXYN tablets contain 5 mg of methamphetamine hydrochloride for oral administration.

Inactive Ingredients:
Corn starch, lactose, sodium benzoate, stearic acid, and talc.

CLINICAL PHARMACOLOGY

Methamphetamine is a sympathomimetic amine with CNS stimulant activity. Peripheral actions include elevation of systolic and diastolic blood pressures and weak bronchodilator and respiratory stimulant action. Drugs of 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 those 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. Other central nervous system actions, or metabolic effect, may be involved, for example.

The mechanism of action involved in producing the beneficial behavioral changes seen in hyperkinetic children receiving methamphetamine is unknown. In humans, methamphetamine is rapidly absorbed from the gastrointestinal tract. The primary site of metabolism is in the liver by aromatic hydroxylation, N-dealkylation, and deamination. At least seven metabolites have been identified in the urine. The biological half-life has been reported in the range of 4 to 5 hours. Excretion occurs primarily in the urine and is dependent on urine pH. About 62% of an oral dose is eliminated in the urine within the first 24 hours with about one-third as intact drug and the remainder as metabolites.

METHAMPHETAMINE HAS A HIGH POTENTIAL FOR ABUSE. IT SHOULD THEREFORE BE FED ONLY IN WEIGHT REDUCTION PROGRAMS FOR PATIENTS IN WHOM ALTERNATIVE THERAPY HAS BEEN IN EFFECTIVE. ADMINISTRATION OF METHAMPHETAMINE FOR PROLONGED PERIODS OF TIME IN OBESITY MAY LEAD TO DRUG DEPENDENCE AND MUST BE AVOIDED. PARTICULAR ATTENTION SHOULD BE PAID TO THE POSSIBILITIES OF SUBSTITUENT OBTAINING METHAMPHETAMINE FOR NON-THERAPEUTIC USE OR DISTRIBUTION TO OTHERS, AND THE DRUG SHOULD BE PRESCRIBED OR DISPENSED SPARINGLY. MISUSE OF METHAMPHETAMINE MAY CAUSE SUDDEN DEATH AND SERIOUS CARDIOVASCULAR ADVERSE EVENTS.
INDICATIONS AND USAGE

Attention Deficit Disorder with Hyperactivity: DESOXYN tablets are indicated as an integral part of a total treatment program which typically includes other medical measures (psychological, educational, social) for the underlying disorder. The use of stimulants should be based on a careful assessment of risk versus benefits. Although some response may occur at lower doses, the recommended starting dose is 0.5 mg. The maintenance dose range is 0.5 mg to 1.5 mg per day for adults and 10 to 20 mg per day for children. Dosage should be individualized and adjusted, if necessary, every 4-7 days based on the child's clinical response and tolerance. In infants, the recommended starting dose is 0.1 mg per kg per day in two divided doses and the maintenance dose range is 0.2 mg per kg per day to 0.5 mg per kg per day in two or more divided doses. Tapering, if necessary, is recommended when discontinuing therapy. Treatment on vacation or weekends is the same as that used during the week. The use of stimulants, like other central nervous system stimulants, should be discontinued (see Drug Abuse and Dependence) if a patient develops a marked increase in symptoms of the attention deficit disorder when the drug is withdrawn.

PHARMACOLOGY

Stimulant Medications: Assessing Cardiovascular Status in Patients being Treated with Stimulant Medications provides important information for the prevention of serious cardiovascular events. Patients who have cardiovascular disease or other serious medical conditions should not be treated with stimulant medications. Adults with such abnormalities should also be considered for treatment with stimulant medications.

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 cases of sudden death may be underlined by other factors, families should be advised of the remote risk of sudden death and should be encouraged to consider the potential benefits of stimulant medications against the potential risk. Adults: Sudden death, stroke, and myocardial infarction have been reported in adults taking stimulant drug at usual doses for ADHD. Although the risk of sudden death in these adult cases is also unknown, adults have a greater likelihood than children of having certain structural cardiac abnormalities, coronary artery disease, or other serious cardiac problems. Adults with such abnormalities should also be generally not be treated with stimulant drug.

Hypertension and Other Cardiovascular Conditions: Stimulant medication causes a modest increase in average blood pressure (about 2-4 mmHg) and average heart rate (about 3-6 bpm) and individuals may have larger changes. 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. Cardiovascular status is indicated in 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. It is also contraindicated in patients taking monoamine oxidase inhibitors or other drugs that cause a serotonin syndrome. Postural hypotension has been reported in association with CNS stimulant treatment at usual doses in children and adolescents. Postural hypotension should be considered when treating patients with stimulant medications. Postural hypotension should be considered when treating patients with stimulant medications.

Serious Cardiovascular Events

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

· Adults: Sudden death, stroke, and myocardial infarction have been reported in adults taking stimulant drug at usual doses for ADHD. Although the risk of sudden death in these adult cases is also unknown, adults have a greater likelihood than children of having certain structural cardiac abnormalities, coronary artery disease, or other serious cardiac problems. Adults with such abnormalities should also generally not be treated with stimulant drug.

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Assessing Cardiovascular Status in Patients being Treated with Stimulant Medications: Children, adolescents, or adults who are being considered for treatment with stimulant medication should have a careful history (including assessment for a family history of cardiovascular disease, the presence of test abnormalities, and physical exam to assess for the presence of cardiac disease) and should undergo further cardiac evaluation if findings suggest such disease (e.g., electrocardiogram and echocardiogram). Patients who develop symptoms such as clinical or electrocardiographic signs of a cardiac nature during stimulant treatment should undergo a comprehensive cardiological evaluation.

Psychiatric Adverse Events

Pre-existing Psychosis: Administration of stimulants may exacerbate symptoms of behavior disturbances and thought disorder in patients with pre-existing psychotic disorders.

Bipolar Illness: Particular care should be taken in using stimulants to treat ADHD in patients with pre-existing 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 pre-existing psychiatric illness should be carefully evaluated.
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
Consistent 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 3 years (to the ages of 10 to 13 years), suggests that treatment for ADHD should be monitored for the appearance of or worsening of aggressive behavior or hostility.

Seizures
There is some clinical evidence that stimulants may lower the convulsive threshold 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 Disturbance
Difficulty with accommodation and blurring of vision have been reported with stimulant treatment.

PRECAUTIONS
General: DESEXYN tablets should be used with caution in patients with even mild hypertension.

Methamphetamine should not be used to combat fatigue or to replace rest in normal persons.

Dosage and Duration: The dosing and duration of methamphetamine should be limited to the smallest amount that is feasible in order to minimize the possibility of misuse or abuse.

Information for Patients: The patient should be informed that methamphetamine may impair the ability to engage in potentially hazardous activities, such as, operating machinery or driving a motor vehicle.

The patient should be cautioned not to increase dosage, except on advice of the physician.

Prescribers should inform patients, their families, and their caregivers about the benefits and risks associated with treatment with methamphetamine and should counsel them to its appropriate use. A patient Medication Guide is available for DESEXYN. The prescriber or health professional should instruct patients, their families, and their caregivers to read the Medication Guide and to obtain answers to any questions they may have. The complete text of the Medication Guide is available at www.ovationpharma.com.

Drug Interactions: In clinical experience in diabetic melanosomes may be altered in association with the use of methamphetamine and the concomitant dopamine agonist.

Methamphetamine may decrease the hypotensive effect of methamphetamine. DESEXYN should not be used concurrently with monoamine oxidase inhibitors (see CONTRAINDICATIONS).

Concurrent administration of tyramine, antihypertensive agents, and indirect-acting sympathomimetic amines such as the amphetamines, should be closely monitored and dosage carefully adjusted.

Phenothiazines can interact in the treatment to antagonize the CNS stimulant action of the amphetamines.

For current labeling information, please visit https://www.fda.gov/drugsatfda
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This label may not be the latest approved by FDA.
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Manifestations of acute overdosage with methamphetamine include restlessness, tremor, hyperreflexia, rapid respiration, confusion, hallucinations, tachycardia, panic state, hyperventilation, and hyperpyrexia. 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 usually terminates in convulsions and coma. Consult with a Certified Poison Control Center regarding treatment for up to date guidelines and advice. Management of acute methamphetamine intoxication is largely symptomatic and includes gastric evacuation, administration of activated charcoal, and sedation. Experience with hemodialysis or peritoneal dialysis is inadequate to permit recommendations in this regard. Acidification of urine increases methamphetamine excretion, but it is believed to increase risk of acute renal failure if myoglobinuria is present. Intravenous phentolamine (Regitine®) has been suggested for possible acute, severe hypertension, if the complications of methamphetamine overdose. Usually a gradual drop in blood pressure will result when sufficient sedation has been achieved. Chlorpromazine has been reported to be useful in decreasing CNS stimulation and sympathomimetic effects.

**DOSAGE AND ADMINISTRATION**

**DESOXYN** tablets are given orally. Methamphetamine should be administered at the lowest effective dosage, and dosage should be individually adjusted. Late evening medication should be avoided because of the resulting insomnia.

Attention Deficit Disorder with Hyperactivity: For treatment of children 6 years or older with a behavioral syndrome characterized by moderate to severe distractibility, short attention span, hyperactivity, emotional lability and impulsivity; an initial dose of 5 mg DESOXYN once or twice a day is recommended. Daily dosage may be raised in increments of 5 mg at weekly intervals until an optimum clinical response is achieved. The usual effective dose is 10 to 25 mg daily. The usual daily dose may be given in two divided doses daily. Where possible, drug administration should be interrupted occasionally to determine if there is a recurrence of behavioral symptoms sufficient to warrant continued therapy.

For Obesity: One 5 mg tablet should be taken one-half hour before each meal. Treatment should not exceed a few weeks in duration. Methamphetamine is not recommended for use as an anorectic agent in children under 12 years of age.

**HOW SUPPLIED**

DESOXYN (methamphetamine hydrochloride tablets, USP) is supplied as white tablets imprinted with the letters OV on one side and the number 12 on the opposite side, containing 5 mg methamphetamine hydrochloride in bottles of 100 (NDC 67386-102-01).

Recommended Storage: Store below 86°F (30°C).

Dispense in a USP tight, light resistant container.

Manufactured by:
Abbott Pharmaceuticals PR Ltd.
Barceloneta, PR 00617

For:
Deerfield, IL 60015, U.S.A.

Revised: March 2007

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Read the Medication Guide that comes with DESOXYN® before you or your child starts taking it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your or your child’s doctor about your or your child’s treatment with DESOXYN.

What is the most important information I should know about DESOXYN?

The following have been reported with use of methamphetamine hydrochloride and other stimulant medicines.

1. Heart-related problems:
   - sudden death in patients who have heart problems or heart defects
   - stroke and heart attack in adults
   - increased blood pressure and heart rate

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

Your or your child’s doctor should check you or your child carefully for heart problems before starting DESOXYN.

Your or your child’s doctor should check you or your child’s blood pressure and heart rate regularly during treatment with DESOXYN.

Call your or your child’s 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 DESOXYN.

2. Mental (Psychiatric) problems:

   All Patients
   - new or worse behavior and thought problems
   - new or worse bipolar illness
   - new or worse aggressive behavior or hostility

   Children and Teenagers
   - new psychotic symptoms (such as hearing voices, believing things that are not true, are suspicious) or new manic symptoms

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

Call your or your child’s doctor right away if you or your child have any new or worsening mental symptoms or problems while taking DESOXYN, especially seeing or hearing things that are not real, believing things that are not real, or are suspicious.

What is DESOXYN?
DESOXYN is a central nervous system stimulant prescription medicine. **It is used for the treatment of Attention-Deficit Hyperactivity Disorder; (ADHD).** DESOXYN may help increase attention and decrease impulsiveness and hyperactivity in patients with ADHD.

DESOXYN should be used as a part of a total treatment program for ADHD that may include counseling or other therapies.

DESOXYN is also used short-term, along with a low calorie diet, for weight loss in obese patients who have not been able to lose weight on other therapies.

**DESOXYN is a federally controlled substance (CII) because it can be abused or lead to dependence. Keep DESOXYN in a safe place to prevent misuse and abuse. Selling or giving away DESOXYN may harm others, and is against the law.**

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

**Who should not take DESOXYN?**

DESOXYN should not be taken if you or your child:

- have heart disease or hardening of the arteries
- have moderate to severe high blood pressure
- have hyperthyroidism
- have an eye problem called glaucoma
- are agitated
- have a history of drug abuse
- are taking or have taken within the past 14 days an antidepressation medicine called a monoamine oxidase inhibitor or MAOI.
- are sensitive to, allergic to, or had a reaction to other stimulant medicines

DESOXYN is not recommended for use in children less than 6 years old in the treatment of ADHD.

**DESOXYN may not be right for you or your child. Before starting DESOXYN tell your or your child’s doctor about all health conditions (or a family history of) including:**

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

Tell your or your child’s doctor if you or your child is pregnant, planning to become pregnant, or breastfeeding.

**Can DESOXYN be taken with other medicines?**

Tell your or your child’s doctor about all of the medicines that you or your child take including prescription and nonprescription medicines, vitamins, and herbal supplements.
DESOXYN 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 DESOXYN. Your or your child’s doctor will decide whether DESOXYN can be taken with other medicines.

(over)
Especially tell your or your child’s doctor if you or your child takes:
• anti-depression medicines including MAOIs
• anti-psychotic medicines
• blood pressure medicines
• insulin
• seizure medicines

Know the medicines that you or your child takes. Keep a list of your medicines with you to show your doctor and pharmacist.

Do not start any new medicine while taking DESOXYN® without talking to your or your child’s doctor first.

How should DESOXYN be taken?
• Take DESOXYN exactly as prescribed. Your or your child’s doctor may adjust the dose until it is right for you or your child.
• DESOXYN is usually taken 1 or 2 times each day.
• From time to time, your or your child’s doctor may stop DESOXYN treatment for a while to check ADHD symptoms.
• Your or your child’s doctor may do regular checks of the blood, heart, and blood pressure while taking DESOXYN. Children should have their height and weight checked often while taking DESOXYN. DESOXYN treatment may be stopped if a problem is found during these check-ups.
• If you or your child takes too much DESOXYN or overdoses, call your or your child’s doctor or poison control center right away, or get emergency treatment.

What are possible side effects of DESOXYN?
See “What is the most important information I should know about DESOXYN?” for information on reported heart and mental problems.

Other serious side effects include:
• slowing of growth (height and weight) in children
• seizures, mainly in patients with a history of seizures
• eyesight changes or blurred vision

Common side effects include:
• fast heart beat
• tremors
• trouble sleeping
• stomach upset
• dry mouth
• decreased appetite
• headache
• dizziness
• weight loss

DESOXYN may affect your or your child’s ability to drive or do other dangerous activities.

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

This is not a complete list of possible side effects. Ask your or your child’s doctor or pharmacist for more information.

How should I store DESOXYN?
• Store DESOXYN in a safe place below 86°F (30°C). Protect from light.
• Keep DESOXYN and all medicines out of the reach of children.
General information about DESOXYN
Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use DESOXYN for a condition for which it was not prescribed. Do not give DESOXYN 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 DESOXYN. If you would like more information, talk with your or your child’s doctor. You can ask your or your child’s doctor or pharmacist for information about DESOXYN that was written for healthcare professionals.
For more information about DESOXYN, contact OVATION Pharmaceuticals at 1-888-514-5204 or visit www.ovationpharma.com.

What are the ingredients in DESOXYN?
Active Ingredient: methamphetamine hydrochloride
Inactive Ingredients: Corn starch, lactose, sodium paraminobenzoate, stearic acid and talc

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