Desoxyn® Ⓒ

(methamphetamine hydrochloride tablets, USP)
Rx only

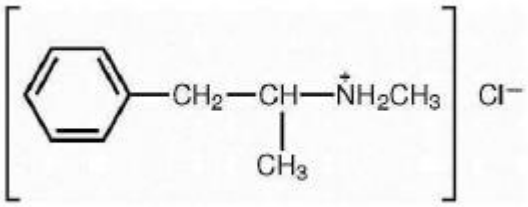
WARNING: ABUSE, MISUSE, AND ADDICTION

DESOXYN has a high potential for abuse and misuse, which can lead to the development of a substance use disorder, including addiction. Misuse and abuse of CNS stimulants, including DESOXYN, can result in overdose and death (see OVERDOSAGE), and this risk is increased with higher doses or unapproved methods of administration, such as snorting or injection.

Before prescribing DESOXYN, assess each patient's risk for abuse, misuse, and addiction. Educate patients and their families about these risks, proper storage of the drug, and proper disposal of any unused drug. Throughout DESOXYN treatment, reassess each patient's risk of abuse, misuse, and addiction and frequently monitor for signs and symptoms of abuse, misuse, and addiction (see WARNINGS and DRUG Abuse AND DEPENDENCE).

DESCRIPTION

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:



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

Inactive Ingredients:
Corn starch, lactose, sodium paraminobenzoate, 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. Other central nervous system actions, or metabolic effects, 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. Alkaline urine will significantly increase the drug halflife. Approximately 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.

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 remedial measures (psychological, educational, social) for a stabilizing effect in children over 6 years of age with a 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 this 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 may not be warranted.

CONTRAINDICATIONS

In patients known to be hypersensitive to amphetamine, or other components of DESOXYN. Hypersensitivity reactions such as angioedema and anaphylactic reactions have been reported in patients treated with other amphetamine products (see **ADVERSE REACTIONS**).

Patients taking monoamine oxidase inhibitors (MAOIs), or within 14 days of stopping MAOIs (including MAOIs such as linezolid or intravenous methylene blue), because of an increased risk of hypertensive crisis (see **WARNINGS and DRUG INTERACTIONS**).

WARNINGS

Abuse, Misuse, and Addiction

DESOXYN has a high potential for abuse and misuse. The use of DESOXYN exposes individuals to the risks of abuse and misuse, which can lead to the development of a substance use disorder, including addiction. DESOXYN can be diverted for non-medical use into illicit channels or distribution (see **DRUG ABUSE** and **DEPENDENCE**: Abuse). Misuse and abuse of CNS stimulants, including DESOXYN can result in overdose and death (see **OVERDOSAGE**), and this risk is increased with higher doses or unapproved methods of administration, such as snorting or injection.

Before prescribing DESOXYN, assess each patient's risk for abuse, misuse, and addiction. Educate patients and their families about these risks and proper disposal of any unused drug. Advise patients to store amphetamine sulfate in a safe place, preferably locked, and instruct patients to not give DESOXYN to anyone else. Throughout DESOXYN treatment, reassess each patient's risk of abuse, misuse, and addiction and frequently monitor for signs and symptoms of abuse, misuse, and addiction.

Risks to Patients with Serious Cardiac Disease

Sudden death has been reported in patients with structural cardiac abnormalities or other serious cardiac disease who are treated with CNS stimulants at the recommended ADHD dosages.

Avoid DESOXYN use in patients with known structural cardiac abnormalities, cardiomyopathy, serious cardiac arrhythmia, coronary artery disease, or other serious cardiac disease.

Increased Blood Pressure and Heart Rate

CNS stimulants cause an increase in blood pressure (mean increase about 2 to 4 mm Hg) and heart rate (mean increase about 3 to 6 bpm). Monitor all patients for potential tachycardia and hypertension.

Psychiatric Adverse Reactions

Exacerbation of Pre-existing Psychosis: CNS stimulants may exacerbate symptoms of behavior disturbance and thought disorder in patients with a pre-existing psychotic disorder

Induction of a Manic Episode in Patients with Bipolar Disease: CNS stimulants may induce a manic or mixed episode in patients. Prior to initiating treatment, screen patients for risk factors for developing a manic episode (e.g., comorbid or history of depressive symptoms or a family history of suicide, bipolar disorder, or depression).

New Psychotic or Manic Symptoms: CNS stimulants, at recommended doses, may cause psychotic or manic symptoms (e.g., hallucinations, delusional thinking, or mania) in patients without a prior history of psychotic illness or mania. In a pooled analysis of multiple short-term, placebo-controlled studies of CNS stimulants, psychotic or manic symptoms occurred in approximately 0.1% of CNS stimulant-treated patients, compared with 0% of placebo-treated patients. If such symptoms occur, consideration discontinuing DESOXYN.

Long-Term Suppression of Growth in Pediatric Patients: CNS stimulants have been associated with weight loss and slowing of growth rate in pediatric patients, including DESOXYN. Closely monitor growth (weight and height) in DESOXYN-treated pediatric patients treated with CNS stimulants.

Pediatric patients who are not growing or gaining height or weight as expected may need to have their treatment interrupted (see **PRECAUTIONS, PEDIATRIC USE**).

Seizures: There is some clinical evidence that stimulants may lower the convulsive threshold in patients with prior history of seizures, in patients with prior EEG abnormalities in absence of seizures, and, very rarely, in patients without a history of seizures and no prior EEG evidence of seizures. In the presence of seizures, the drug should be discontinued.

Peripheral Vasculopathy, including Raynaud's phenomenon: Stimulants, including DESOXYN, used to treat ADHD are associated with peripheral vasculopathy, including

Raynaud's phenomenon. Signs and symptoms are usually intermittent and mild; however, sequelae have included digital ulceration and/or soft tissue breakdown. Effects of peripheral vasculopathy, including Raynaud's phenomenon, were observed in postmarketing eports and at therapeutic dosages in all age groups throughout the course of treatment. Signs and symptoms generally improve after dosage reduction in dose- or discontinuation of the CNS stimulant. Careful observation for digital changes is necessary during DESOXYN treatment. Further clinical evaluation (e.g., rheumatology referral) may be appropriate for DESOXYN-treated patients who develop signs or symptoms of peripheral vasculopathy.

Serotonin Syndrome

Serotonin syndrome, a potentially life-threatening reaction, may occur when amphetamines are used in combination with other drugs that affect the serotonergic neurotransmitter systems such as monoamine oxidase inhibitors (MAOIs), selective serotonin reuptake inhibitors (SSRIs), serotonin norepinephrine reuptake inhibitors (SNRIs), triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, tryptophan, buspirone, and St. John's Wort (see **DRUG INTERACTIONS**). Amphetamines and amphetamine derivatives are known to be metabolized, to some degree, by cytochrome P450 2D6 (CYP2D6) and display minor inhibition of CYP2D6 metabolism (see **CLINICAL PHARMACOLOGY**). The potential for a pharmacokinetic interaction exists with the coadministration of CYP2D6 inhibitors which may increase the risk with increased exposure to DESOXYN. In these situations, consider an alternative nonserotonergic 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 DESOXYN with MAOI drugs is contraindicated (see **CONTRAINDICATIONS**).

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

Motor and Verbal Tics, and Worsening of Tourette's Syndrome

CNS stimulants, including amphetamine sulfate, have been associated with the onset or exacerbation of motor and verbal tics. Worsening of Tourette's syndrome has also been reported. Before initiating DESOXYN, assess the family history and clinically evaluate patients for tics or Tourette's syndrome. Regularly monitor patients for the emergence or worsening of tics or Tourette's syndrome with DESOXYN, and discontinue treatment if clinically appropriate.

PRECAUTIONS

General:
DESOXYN 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.

Prescribing and dispensing of methamphetamine should be limited to the smallest amount that is feasible at one time in order to minimize the possibility of overdosage.

Information for Patients:

Advise the patient to read the FDA-approved patient labeling (Medication Guide).

Abuse, Misuse, and Addiction

Educate patients and their families about the risks of abuse, misuse, and addiction of DESOXYN, which can lead to overdose and death, and proper disposal of any unused drug (see WARNINGS, DRUG ABUSE AND DEPENDENCE, and OVERDOSAGE). Advise patients to store DESOXYN in a safe place, preferably locked, and instruct patients to not give DESOXYN to anyone else.

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.

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

- Instruct patients beginning treatment with DESOXYN 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 DESOXYN.
- Further clinical evaluation (e.g., rheumatology referral) may be appropriate for certain patients.

Motor and Verbal Tics, and Worsening of Tourette's Syndrome

- Advise patients that motor and verbal tics and worsening of Tourette's Syndrome may occur during treatment with DESOXYN. Instruct the patients to notify their healthcare provider if emergence or worsening of tics or Tourette's syndrome occurs (see **WARNINGS**).

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

Drug Interactions: Insulin requirements in diabetes mellitus may be altered in association with the use of methamphetamine and the concomitant dietary regimen.

Methamphetamine may decrease the hypotensive effect of guanethidine.

DESOXYN should not be used concurrently with monoamine oxidase inhibitors (see **CONTRAINDICATIONS**).

Concurrent administration of *tricyclic antidepressants* and indirect-acting sympathomimetic amines such as the amphetamines, should be closely supervised and dosage carefully adjusted.

Phenothiazines are reported in the literature to antagonize the CNS stimulant action of the amphetamines.

Drug/Laboratory Test Interactions: Literature reports suggest that amphetamines may be associated with significant elevation of plasma corticosteroids. This should be considered if determination of plasma corticosteroid levels is desired in a person receiving amphetamines.

Acidifying Agents

Lower blood levels and efficacy of amphetamines. Increase dose based on clinical response. Examples of acidifying agents include gastrointestinal acidifying agents (e.g., guanethidine, reserpine, glutamic acid HCl, ascorbic acid) and urinary acidifying agents (e.g., ammonium chloride, sodium acid phosphate, methenamine salts).

Alkalinizing Agents
Increase blood levels and potentiate the action of amphetamine. Co-administration of DESOXYN and gastrointestinal alkalinizing agents should be avoided. Examples of alkalinizing agents include gastrointestinal alkalinizing agents (e.g., sodium bicarbonate) and urinary alkalinizing agents (e.g., acetazolamide, some thiazides).

Tricyclic Antidepressants
May enhance the activity of tricyclic or sympathomimetic agents causing striking and sustained increases in the concentration of d-amphetamine in the brain; cardiovascular effects can be potentiated. Monitor frequently and adjust or use alternative therapy based on clinical response. Examples of tricyclic antidepressants include desipramine, Protriptyline.

CYP2D6 Inhibitors
The concomitant use of DESOXYN and CYP2D6 inhibitors may increase the exposure of DESOXYN 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 DESOXYN initiation and after a dosage increase. If serotonin syndrome occurs, discontinue DESOXYN and the CYP2D6 inhibitor (see **WARNINGS, OVERDOSAGE**). Examples of CYP2D6 Inhibitors include paroxetine and fluoxetine (also serotonergic drugs), quinidine, ritonavir.

Serotonergic Drugs
The concomitant use of DESOXYN 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 DESOXYN initiation or dosage increase. If serotonin syndrome occurs, discontinue DESOXYN and the concomitant serotonergic drug(s) (see **WARNINGS and PRECAUTIONS**). Examples of serotonergic drugs include selective serotonin reuptake inhibitors

(SSRI), serotonin norepinephrine reuptake inhibitors (SNRI), triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, tryptophan, buspirone, St. John's Wort.

MAO Inhibitors
Concomitant use of MAOIs and CNS stimulants can cause hypertensive crisis. Potential outcomes include death, stroke, myocardial infarction, aortic dissection, ophthalmological complications, eclampsia, pulmonary edema, and renal failure. Do not administer DESOXYN concomitantly or within 14 days after discontinuing MAOI (see **CONTRAINDICATIONS** and **WARNINGS**). Examples of MAOIs include selegiline, tranylcypromine, isocarboxazid, phenelzine, linezolid, methylene blue.

Proton Pump Inhibitors
Time to maximum concentration (Tmax) of amphetamine is decreased compared to when administered alone. Monitor patients for changes in clinical effect and adjust therapy based on clinical response. An example of a proton pump inhibitor is omeprazole.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Data are not available on longterm potential for carcinogenicity, mutagenicity, or impairment of fertility.

Pregnancy
Teratogenic effects: Pregnancy Category C. Methamphetamine has been shown to have teratogenic and embryocidal effects in mammals given high multiples of the human dose. There are no adequate and well-controlled studies in pregnant women. DESOXYN tablets should not be used during pregnancy unless 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.

Usage in Nursing Mothers: Amphetamines are excreted in human milk. Mothers taking amphetamines should be advised to refrain from nursing.

Pediatric Use: Long-term effects of methamphetamine in children have not been established (see **WARNINGS**).

Drug treatment is not indicated in all cases of the behavioral syndrome characterized by moderate to severe distractibility, short attention span, hyperactivity, emotional lability and impulsivity. It should be considered only in light of the complete history and evaluation of the child. The decision to prescribe DESOXYN tablets 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 DESOXYN tablets is usually not indicated.

Clinical experience suggests that in psychotic children, administration of DESOXYN tablets 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.

Geriatric Use: Clinical Studies of DESOXYN did not include sufficient numbers of subjects age 65 years and over to determine whether elderly subjects respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal or cardiac function, and of concomitant disease or other drug therapy observed in this population.

ADVERSE REACTIONS

The following are adverse reactions in decreasing order of severity within each category that have been reported:

Cardiovascular: Elevation of blood pressure, tachycardia and palpitation. Fatal cardiorespiratory arrest has been reported, mostly in the context of abuse/misuse.

Central Nervous System: Psychotic episodes have been rarely reported at recommended doses. Dizziness, dysphoria, overstimulation, euphoria, insomnia, tremor, restlessness and headache. Exacerbation of motor and verbal tics and Tourette's syndrome.

Gastrointestinal: Diarrhea, constipation, dryness of mouth, unpleasant taste, intestinal ischemia, and other gastrointestinal disturbances.

Hypersensitivity: Urticaria.

Endocrine: Impotence and changes in libido; frequent or prolonged erections.

Musculoskeletal: Rhabdomyolysis.

Miscellaneous: Suppression of growth has been reported with the long-term use of stimulants in children (see WARNINGS).

Skin and Subcutaneous Tissue Disorders: Alopecia.

To report SUSPECTED ADVERSE REACTIONS, contact Recordati Rare Diseases Inc. at 1-888-575-8344 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG ABUSE AND DEPENDENCE

Controlled Substance

DESOXYN is a Schedule II controlled substance.

Abuse

DESOXYN has a high potential for abuse and misuse which can lead to the development of a substance use disorder, including addiction [see Warnings and Precautions]. DESOXYN can be diverted for non-medical use into illicit channels or distribution.

Abuse is the intentional non-therapeutic use of a drug, even once, to achieve a desired psychological or physiological effect. Misuse is the intentional use, for therapeutic purposes, of a drug by an individual in a way other than prescribed by a health care provider or for whom it was not prescribed. Drug addiction is a cluster of behavioral, cognitive, and physiological phenomena that may include a strong desire to take the drug, difficulties in controlling drug use (e.g., continuing drug use despite harmful consequences, giving a higher priority to drug use than other activities and obligations), and possible tolerance or physical dependence.

Misuse and abuse of methamphetamine may cause increased heart rate, respiratory rate, or blood pressure; sweating; dilated pupils; hyperactivity; restlessness; insomnia; decreased appetite; loss of coordination; tremors; flushed skin; vomiting; and/or abdominal pain. Anxiety, psychosis, hostility, aggression, and suicidal or homicidal ideation have also been observed with CNS stimulants abuse and/or misuse. Misuse and abuse of CNS stimulants, including DESOXYN, can result in overdose and death [see Overdosage], and this risk is increased with higher doses or unapproved methods of administration, such as snorting or injection.

Dependence

Physical Dependence

DESOXYN may produce physical dependence. Physical dependence is a state that develops as a result of physiological adaptation in response to repeated drug use, manifested by withdrawal signs and symptoms after abrupt discontinuation or a significant dose reduction of a drug.

Withdrawal signs and symptoms after abrupt discontinuation or dose reduction following prolonged use of CNS stimulants including DESOXYN include dysphoric mood; depression; fatigue; vivid, unpleasant dreams; insomnia or hypersomnia; increased appetite; and psychomotor retardation or agitation.

Tolerance

DESOXYN may produce tolerance. Tolerance is a physiological state characterized by a reduced response to a drug after repeated administration (i.e., a higher dose of a drug is required to produce the same effect that was once obtained at a lower dose).

OVERDOSAGE

Clinical Effects of Overdose

Overdose of CNS stimulants is characterized by the following sympathomimetic effects:

- Cardiovascular effects including tachyarrhythmias, and hypertension or hypotension. Vasospasm, myocardial infarction, or aortic dissection may precipitate sudden cardiac death. Takotsubo cardiomyopathy may develop.

- CNS effects including psychomotor agitation, confusion, and hallucinations. Serotonin syndrome, seizures, cerebral vascular accidents, and coma may occur.
- Life-threatening hyperthermia (temperatures greater than 104°F) and rhabdomyolysis may develop.

Overdose Management
Consider the possibility of multiple drug ingestion. D-amphetamine is not dialyzable.

Consider contacting the Poison Help line (1-800-222-1222) or a medical toxicologist for additional overdose management recommendations.

DOSAGE AND ADMINISTRATION
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.

Prior to treating patients with DESOXYN, assess:

- for the presence of cardiac disease (i.e., perform a careful history, family history of sudden death or ventricular arrhythmia, and physical exam) (see WARNINGS).
- the family history and clinically evaluate patients for motor or verbal tics or Tourette's syndrome (see WARNINGS).

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 20 to 25 mg daily. The total daily dose may be given in two divided doses daily.

HOW SUPPLIED
DESOXYN (methamphetamine hydrochloride tablets, USP) is supplied as white tablets imprinted with the letter R on one side and the number 12 on the opposite side, containing 5 mg methamphetamine hydrochloride in bottles of 100 (NDC 55292-104-01).

Recommended Storage: Store at 20°C to 25°C (68°F to 77°F). See USP controlled room temperature.

Dispense in a USP tight, light resistant container.

Manufactured by:
UPM Pharmaceuticals
510 5th Street, Bristol, TN 37620, U.S.A.
For: Recordati Rare Diseases Inc., Lebanon, NJ 08833, U.S.A.

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This product label may have been updated. For the most recent prescribing information, please visit www.recordatirarediseases.com.

Revised: October 2023

MEDICATION GUIDE
Desoxyn®
(De-soks-in)
(methamphetamine hydrochloride tablets) CII

What is the most important information I should know about DESOXYN?
DESOXYN may cause serious side effects, including:

- **Abuse, misuse, and addiction**. DESOXYN has a high chance for abuse and misuse and may lead to substance use problems, including addiction. Misuse and abuse of DESOXYN, other amphetamine containing medicines, and methylphenidate containing medicines, can lead to overdose and death. The risk of overdose and death is increased with higher doses of DESOXYN or when it is used in ways that are not approved, such as snorting or injection.
  - Your healthcare provider should check your child's risk for abuse, misuse, and addiction before starting treatment with DESOXYN and will monitor your child during treatment.
  - DESOXYN may lead to physical dependence after prolonged use, even if taken as directed by your healthcare provider.
  - Do not give DESOXYN to anyone else. See **"What is DESOXYN?"** for more information.
  - Keep DESOXYN in a safe place and properly dispose of any unused medicine. See **"How should I store DESOXYN?"** for more information.
  - Tell your healthcare provider if your child has ever abused or been dependent on alcohol, prescription medicines, or street drugs.
- **Risks for people with serious heart disease**. Sudden death has happened in people who have heart defects or other serious heart disease.

Your child's healthcare provider should check your child carefully for heart problems before starting treatment with DESOXYN. Tell your child's healthcare provider if your child has any heart problems, heart disease, or heart defects.

Call your child's healthcare provider or go to the nearest hospital emergency room right away if your child has any signs of heart problems such as chest pain, shortness of breath, or fainting during treatment with DESOXYN.

- **Increased blood pressure and heart rate.** Your child's healthcare provider should check your child's blood pressure and heart rate regularly during treatment with DESOXYN.

- **Mental (psychiatric) problems, including:**
  - new or worse behavior and thought problems
  - new or worse bipolar illness
  - new psychotic symptoms (such as hearing voices or seeing or believing things that are not real) or new manic symptoms

Tell your child's healthcare provider about any mental problems your child has, or about a family history of suicide, bipolar illness, or depression.

Call your child's healthcare provider right away if your child has any new or worsening mental symptoms or problems during treatment with DESOXYN, especially hearing voices, seeing or believing things that are not real, or new manic symptoms.

What is DESOXYN?

DESOXYN is a central nervous system (CNS) stimulant prescription medicine used for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in children 6 years to 17 years of age. DESOXYN may help increase attention and decrease impulsiveness and hyperactivity in people with ADHD.

It is not known if DESOXYN is safe and effective in children under 6 years of age.

DESOXYN is a federally controlled substance (CII) because it contains methamphetamine that can be a target for people who abuse prescription medicines or street drugs. Keep DESOXYN in a safe place to protect it from theft. Never give your DESOXYN to anyone else because it may cause death or harm them. Selling or giving away DESOXYN may harm others and is against the law.

Do not take DESOXYN if your child is:

- allergic to amphetamine or any of the ingredients in DESOXYN. See the end of this Medication Guide for a complete list of ingredients in DESOXYN.
- taking, or has stopped taking within the past 14 days, a medicine used to treat depression called a monoamine oxidase inhibitor (MAOI).

Before taking DESOXYN, tell your child's healthcare provider about all your child's medical conditions, including if your child:

- has heart problems, heart disease, heart defects, or high blood pressure
- has mental problems including psychosis, mania, bipolar illness or depression, or a family history of suicide bipolar illness, or depression
- has circulation problems in fingers and toes
- has kidney problems
- have or had repeated movements or sounds (tics) or Tourette's syndrome, or have a family history of tics or Tourette's syndrome
- is pregnant or plans to become pregnant. DESOXYN may harm the unborn baby.
  - o **Pregnancy Exposure Registry:** There is a pregnancy registry for women who are exposed to DESOXYN during pregnancy. The purpose of the registry is to collect information about the health of women exposed to DESOXYN and their baby. If your child becomes pregnant during treatment with DESOXYN, talk to your child's healthcare provider about registering with the National Pregnancy Registry for Psychostimulants at 1-866-961-2388 or by visiting online at https://womensmentalhealth.org/clinical-and-researchprograms/pregnancyregistry/othermedications/
- is breastfeeding or plans to breastfeed. DESOXYN passes into breast milk. Your child should not breastfeed during treatment with DESOXYN. Talk to your child's healthcare provider about the best way to feed the baby during treatment with DESOXYN.

Tell your child's healthcare provider about all of the medicines that your child takes including prescription and over-the-counter 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 changed during treatment with

DESOXYN. Your child's healthcare provider will decide whether DESOXYN can be taken with other medicines.

Especially tell your child's healthcare provider if your child takes:

- medicines used to treat migraine headaches known as triptans
- tricyclic antidepressants
- fentanyl
- lithium
- tramadol
- tryptophan
- buspirone
- St. John's Wort
- medicines used to treat mood, anxiety, psychotic or thought disorders, including selective serotonin reuptake inhibitors (SSRIs) and serotonin norepinephrine reuptake inhibitors (SNRIs)

Ask your child's healthcare provider if you are not sure if your child takes any of these medicines. Know the medicines your child takes. Keep a list of your child's medicines with you to show your child's healthcare provider and pharmacist. **Do not start any new medicine during treatment with DESOXYN without talking to your child's healthcare provider first**.

How should DESOXYN be taken?

- Take DESOXYN exactly as prescribed.
- Your child's healthcare provider may change the dose or have your child stop taking DESOXYN if needed.
- DESOXYN is usually taken 1 or 2 times each day. Avoid taking DESOXYN late in the evening because it may cause sleep problems.

If your child takes too much DESOXYN, call your child's healthcare provider or Poison Help line at 1-800-222-1222 or go to the nearest hospital emergency room right away.

What are possible side effects of DESOXYN?

DESOXYN may cause serious side effects, including:

- See **"What is the most important information I should know about DESOXYN?"**
- **Slowing of growth (height and weight) in children.** Children should have their height and weight checked often during treatment with DESOXYN. DESOXYN treatment may be stopped if your child is not growing or gaining weight.
- **Circulation problems in fingers and toes (peripheral vasculopathy, including Raynaud's phenomenon)**. Signs and symptoms may include:
  - o fingers or toes may feel numb, cool, painful
  - o fingers or toes may change color from pale, to blue, to red

Tell your child's healthcare provider if your child has numbness, pain, skin color change, or sensitivity to temperature in your fingers or toes or if your child has any signs of unexplained wounds appearing on fingers or toes during treatment with DESOXYN.

- **Serotonin syndrome**. This problem may happen when DESOXYN is taken with certain other medicines and may be life-threatening. Call your healthcare provider or go to the nearest hospital emergency room if you have any of the following symptoms of serotonin syndrome:
  - o agitation, hallucinations, coma
  - o changes in blood pressure
  - o high body temperature
  - o dizziness
  - o sweating or fever
  - o muscle stiffness or tightness
  - o fast heartbeat
  - o flushing
  - o seizures
  - o nausea, vomiting, diarrhea
  - o loss of coordination
  - o confusion
- **New or worsening tics or worsening Tourette's syndrome.** Tell your healthcare provider if you or your child get any new or worsening tics or worsening Tourette's syndrome during treatment with DESOXYN.

The most common side effects with DESOXYN include:

- fast heartbeat or heart beating harder than normal
- dizziness
- trouble sleeping
- shaking
- headache
- diarrhea
- dry mouth

These are not all the possible side effects of DESOXYN.

Call your child's doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store DESOXYN?

- Store DESOXYN at room temperature between 68°F to 77°F (20°C to -25°C).
- Store DESOXYN in a safe place like a locked cabinet. Protect from light.
- Dispose of remaining, unused, or expired DESOXYN by a medicine take-back program at a U.S. Drug Enforcement Administration (DEA) authorized collection site. If no take-back program or DEA authorized collector is available, mix DESOXYN with an undesirable, nontoxic substance such as dirt, cat litter, or used coffee grounds to make it less appealing to children and pets. Place the mixture in a container such as a sealed plastic bag and throw away DESOXYN in the household trash. Visit www.fda.gov/drugdisposal for additional information on disposal of unused medicines.

Keep DESOXYN and all medicines out of the reach of children.

General information about the safe and effective use of 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 symptoms that your child has. It may harm them and it is against the law.

You can ask your child's pharmacist or healthcare provider for information about DESOXYN that is written for healthcare professionals.

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

Recordati Rare Diseases Inc.
Lebanon, NJ 08833, U.S.A.

For more information about DESOXYN go to www.recordatirarediseases.com or call contact Recordati Rare Diseases Inc. at 1-888-575-8344.

This Medication Guide has been approved by the U.S. Food and Drug Administration. Revised: 10/2023