MEDICATION GUIDE C II

Desoxyn®

(Pronounced Dĕ-sŏks-ĭn)
(methamphetamine hydrochloride tablets, USP)

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.

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

- fingers or toes may feel numb, cool, painful
- fingers or toes may change color from pale, to blue, to red

Tell your doctor if you have or your child has numbness, pain, skin color change, or sensitivity to temperature in your fingers or toes.

Call you your doctor right away if you have or your child has any signs of unexplained wounds appearing on fingers or toes while taking DESOXYN.

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 antidepression 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)
- circulation problems in fingers and toes

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.

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.

Call your or 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 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 Recordati Rare Diseases Inc. at 1-888-575-8344 or visit www.recordatirarediseases.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.

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