

## **MEDICATION GUIDE**

### **FOCALIN<sup>®</sup>**

**(dexamethylphenidate hydrochloride tablets) CII**

Read the Medication Guide that comes with FOCALIN<sup>®</sup> 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 doctor about your or your child's treatment with FOCALIN<sup>®</sup>.

#### **What is the most important information I should know about FOCALIN<sup>®</sup>?**

**The following have been reported with use of dexamethylphenidate 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 doctor if you or your child have any heart problems, heart defects, high blood pressure, or a family history of these problems.

Your doctor should check you or your child carefully for heart problems before starting FOCALIN®.

Your doctor should check your or your child's blood pressure and heart rate regularly during treatment with FOCALIN®.

**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 FOCALIN®.**

## **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 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 FOCALIN®, especially seeing or hearing things that are not real, believing things that are not real, or are suspicious.**

## **What Is FOCALIN®?**

FOCALIN® is a central nervous system stimulant prescription medicine. **It is used for the treatment of attention deficit and hyperactivity disorder (ADHD).** FOCALIN® may help increase attention and decrease impulsiveness and hyperactivity in patients with ADHD.

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

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

Tell your 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 FOCALIN®?**

**FOCALIN® should not be taken if you or your child:**

- are very anxious, tense, or agitated
- have an eye problem called glaucoma
- have tics or Tourette's syndrome, or a family history of Tourette's syndrome. Tics are hard to control repeated movements or sounds.

- are taking or have taken within the past 14 days an anti-depression medicine called a monoamine oxidase inhibitor or MAOI.
- are allergic to anything in FOCALIN<sup>®</sup>. See the end of this Medication Guide for a complete list of ingredients.

FOCALIN<sup>®</sup> should not be used in children less than 6 years old because it has not been studied in this age group.

**FOCALIN<sup>®</sup> may not be right for you or your child. Before starting FOCALIN<sup>®</sup> 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
- seizures or have had an abnormal brain wave test (EEG)

Tell your doctor if you or your child is pregnant, planning to become pregnant, or breast-feeding.

### **Can FOCALIN<sup>®</sup> be taken with other medicines?**

**Tell your doctor about all of the medicines that you or your child take including prescription and nonprescription medicines, vitamins, and herbal supplements.** FOCALIN<sup>®</sup> 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 FOCALIN<sup>®</sup>.

Your doctor will decide whether FOCALIN<sup>®</sup> can be taken with other medicines.

### **Especially tell your doctor if you or your child takes:**

- anti-depression medicines including MAOIs
- seizure medicines
- blood thinner medicines
- blood pressure medicines
- cold or allergy medicines that contain decongestants

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 FOCALIN<sup>®</sup> without talking to your doctor first.**

### **How should FOCALIN<sup>®</sup> be taken?**

- **Take FOCALIN exactly as prescribed.** Your doctor may adjust the dose until it is right for you or your child.
- Take FOCALIN<sup>®</sup> twice a day, at least 4 hours apart.
- FOCALIN<sup>®</sup> can be taken with or without food.
- From time to time, your doctor may stop FOCALIN<sup>®</sup> treatment for a while to check ADHD symptoms.
- Your doctor may do regular checks of the blood, heart, and blood pressure while taking FOCALIN<sup>®</sup>. Children should have their height and weight checked often while taking FOCALIN<sup>®</sup>. FOCALIN<sup>®</sup> treatment may be stopped if a problem is found during these check-ups.
- **If you or your child takes too much FOCALIN<sup>®</sup> or overdoses, call your doctor or poison control center right away, or get emergency treatment.**

### **What are possible side effects of FOCALIN<sup>®</sup>?**

See "What is the most important information I should know about FOCALIN<sup>®</sup>?" 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:**

- stomach ache
- decreased appetite
- nausea
- fever

Talk to your 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 doctor or pharmacist for more information.

**How should I store FOCALIN®?**

- Store FOCALIN® in a safe place at room temperature, 59 to 86° F (15 to 30° C).
- **Keep FOCALIN® and all medicines out of the reach of children.**

**General information about FOCALIN®**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use FOCALIN® for a condition for which it was not prescribed. Do not give FOCALIN® 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 FOCALIN®. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about FOCALIN® that was written for healthcare professionals. For more information about FOCALIN® call 1-888-669-6682.

**What are the ingredients in FOCALIN®?**

**Active Ingredient:** dexamethylphenidate hydrochloride

**Inactive Ingredients:** pregelatinized starch, lactose monohydrate, sodium starch glycolate, microcrystalline cellulose, magnesium stearate, and FD&C Blue No.1 #5516 aluminum lake (2.5 mg tablets), D&C Yellow Lake #10 (5 mg tablets); the 10 mg tablet contains no dye.

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

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

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