

MEDICATION GUIDE

FOCALIN[®]

(dexamethylphenidate hydrochloride tablets) CII

Read the Medication Guide that comes with FOCALIN[®] 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[®].

What is the most important information I should know about FOCALIN[®]?

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®. See the end of this Medication Guide for a complete list of ingredients.

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

FOCALIN® may not be right for you or your child. Before starting FOCALIN® 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® 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® 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®.

Your doctor will decide whether FOCALIN® 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® without talking to your doctor first.

How should FOCALIN® be taken?

- **Take FOCALIN exactly as prescribed.** Your doctor may adjust the dose until it is right for you or your child.
- Take FOCALIN® twice a day, at least 4 hours apart.
- FOCALIN® can be taken with or without food.
- From time to time, your doctor may stop FOCALIN® treatment for a while to check ADHD symptoms.

- Your doctor may do regular checks of the blood, heart, and blood pressure while taking FOCALIN®. Children should have their height and weight checked often while taking FOCALIN®. FOCALIN® treatment may be stopped if a problem is found during these check-ups.
- **If you or your child takes too much FOCALIN® or overdoses, call your doctor or poison control center right away, or get emergency treatment.**

What are possible side effects of FOCALIN®?

See “**What is the most important information I should know about FOCALIN®?**” for information on reported heart and mental problems.

Other serious side effects include:

- Serious allergic reactions (symptoms can be difficulty breathing, swelling of the face, neck and throat, rashes and hives, fever)
- 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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