

Patients Currently Using Methylphenidate

For patients currently using methylphenidate, the recommended starting dose of Focalin is half the dose of racemic methylphenidate. The maximum recommended dose is 20 mg/day (10 mg twice daily).

Maintenance/Extended Treatment

There is no body of evidence available from controlled trials to indicate how long the patient with ADHD should be treated with Focalin. It is generally agreed, however, that pharmacological treatment of ADHD may be needed for extended periods. Nevertheless, the physician who elects to use Focalin for extended periods in patients with ADHD should periodically re-evaluate the long-term usefulness of the drug for the individual patient with periods off medication to assess the patient's functioning without pharmacotherapy. Improvement may be sustained when the drug is either temporarily or permanently discontinued.

Dose Reduction and Discontinuation

If paradoxical aggravation of symptoms or other adverse events occur, the dosage should be reduced, or, if necessary, the drug should be discontinued.

If improvement is not observed after appropriate dosage adjustment over a 1-month period, the drug should be discontinued.

HOW SUPPLIED

Tablets, D-shaped, embossed "D" on upper convex face and dosage strength on lower convex face

2.5 mg Tablets - blue

Bottles of 100.....NDC 0078-0380-05

5 mg Tablets - yellow

Bottles of 100.....NDC 0078-0381-05

10 mg Tablets - white

Bottles of 100.....NDC 0078-0382-05

Store at 25°C (77°F); excursions permitted 15°C-30°C (59°F-86°F).

[see USP Controlled Room Temperature]

Protect from light and moisture.

REFERENCE

American Psychiatric Association. Diagnosis and Statistical Manual of Mental Disorders. 4th ed. Washington DC: American Psychiatric Association 1994.

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 dexmethylphenidate 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.

3. Circulation problems in fingers and toes [Peripheral vasculopathy, including Raynaud's phenomenon]: fingers or toes may feel numb, cool, painful, and/or 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 your doctor right away if you have or your child has any signs of unexplained wounds appearing on fingers or toes while taking Focalin**

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)
- circulation problems in fingers or toes

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
- Painful and prolonged erections (priapism) have occurred with methylphenidate. If you or your child develop priapism, seek medical help right away. Because of the potential for lasting damage, priapism should be evaluated by a doctor immediately.

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.

Manufactured for:

Novartis Pharmaceuticals Corporation

East Hanover, NJ 07936

By:

Mikart, Inc.

Atlanta, GA 30318

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