

MEDICATION GUIDE
FOCALIN XR® (foh-kuh-lin XR)
(dexamethylphenidate hydrochloride, USP)
extended-release capsules CII

What is the most important information I should know about FOCALIN XR?

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

Tell your doctor if you or your child have abused or been dependent on alcohol, prescription medicines, or street drugs.

The following have been reported with use of methylphenidate 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 XR.

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

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 XR.

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**
- **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 XR, especially seeing or hearing things that are not real, believing things that are not real, or are suspicious.

What is FOCALIN XR?

- FOCALIN XR is a central nervous system stimulant (CNS) prescription medicine. **It is used for the treatment of Attention-Deficit Hyperactivity Disorder (ADHD).** FOCALIN XR may help increase attention and decrease impulsiveness and hyperactivity in patients with ADHD.
- FOCALIN XR should be used as a part of a total treatment program for ADHD that may include counseling or other therapies.

Who should not take FOCALIN XR:

FOCALIN XR should not be taken if you or your child:

- are allergic to methylphenidate hydrochloride, or any of the ingredients in FOCALIN XR. See the end of this Medication Guide for a complete list of ingredients in FOCALIN XR.
- are taking or have taken within the past 14 days an anti-depression medicine called a monoamine oxidase inhibitor or MAOI.

FOCALIN XR may not be right for you or your child. Before starting FOCALIN XR, 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
- circulation problems in fingers or toes
- if you are pregnant or plan to become pregnant. It is not known if FOCALIN XR will harm your unborn baby.
 - There is a pregnancy registry for females who are exposed to ADHD medications, including FOCALIN XR, during pregnancy. The purpose of the registry is to collect information about the health of females exposed to FOCALIN XR and their baby. If you or your child becomes pregnant during treatment with FOCALIN XR, talk to your healthcare provider about registering with the National Pregnancy Registry of ADHD medications at 1-866-961-2388 or visit online at <https://womensmentalhealth.org/adhd-medications/>.
- if you are breastfeeding or plan to breastfeed. FOCALIN XR passes into your breast milk. Talk to your healthcare provider about the best way to feed the baby during treatment with FOCALIN XR.

Tell your doctor about all of the medicines that you or your child takes, including prescription and over-the-counter medicines, vitamins, and herbal supplements. FOCALIN XR 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 XR.

Your doctor will decide whether FOCALIN XR can be taken with other medicines.

Especially tell your doctor if you or your child takes:

- anti-depression medicines, including MAOIs
- blood pressure medicines (anti-hypertensive)

Know the medicines that you or your child takes. Keep a list of your medicines with you to show your doctor and pharmacist.

- You should not take FOCALIN XR on the day of your operation if a certain type of anesthetic is used. This is because there is a chance of a sudden rise in blood pressure and heart rate during the operation.

Do not start any new medicine while taking FOCALIN XR without talking to your doctor first.

How should FOCALIN XR be taken?

- Take FOCALIN XR exactly as prescribed. Your doctor may adjust the dose until it is right for you or your child.
- Take FOCALIN XR once each day in the morning. FOCALIN XR is an extended-release capsule.
- FOCALIN XR can be taken with or without food. Taking FOCALIN XR with food may slow the time it takes for the medicine to start working.
- Swallow FOCALIN XR capsules whole with water or other liquids. **Do not chew, crush, or divide the capsules or the beads in the capsule.** If you or your child cannot swallow the capsule, open it and sprinkle the small beads of medicine over a spoonful of applesauce and swallow it right away without chewing.
- From time-to-time, your doctor may stop FOCALIN XR treatment for a while to check ADHD symptoms.
- Your doctor may do regular checks of the blood, heart, and blood pressure while taking FOCALIN XR.
- Children should have their height and weight checked often while taking FOCALIN XR. FOCALIN XR treatment may be stopped if a problem is found during these check-ups.
- **In case of poisoning, call your poison control center at 1-800-222-1222 right away, or go to the nearest hospital emergency room.**

What are the possible side effects of FOCALIN XR?

FOCALIN XR may cause serious side effects, including:

- see **“What is the most important information I should know about FOCALIN XR?”** for information on reported heart and mental problems.
- **painful and prolonged erections (priapism)** have occurred with methylphenidate. If you or your child develops priapism, seek medical help right away. Because of the potential for lasting damage, priapism should be evaluated by a doctor immediately.
- **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 or your child have, numbness, pain, skin color change, or sensitivity to temperature in the 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 XR.**
- **Slowing of growth (height and weight) in children**

Common side effects include:

Children (6–17 years)

- **dyspepsia**
- decreased appetite
- headache
- anxiety

Adults

- dry mouth
- dyspepsia
- headache
- anxiety
- pharyngolaryngeal pain

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

How should I store FOCALIN XR?

- Store FOCALIN XR in a safe place and in a tightly closed container at room temperature between 68°F to 77°F (20°C to 25°C).
- Dispose of remaining, unused, or expired FOCALIN XR by a medicine take-back program at authorized collection sites, such as retail pharmacies, hospital or clinic pharmacies, and law enforcement locations. If no take-back program or authorized collector is available, mix FOCALIN XR 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 (discard) FOCALIN XR in the household trash.
- **Keep FOCALIN XR and all medicines out of the reach of children.**

General information about the safe and effective use of FOCALIN XR.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. You can ask your pharmacist or doctor for information about FOCALIN XR that is written for healthcare professionals. Do not use FOCALIN XR for a condition for which it was not prescribed. Do not give FOCALIN XR to other people, even if they have the same symptoms that you have. It may harm them and it is against the law.

What are the ingredients in FOCALIN XR?

Active ingredient: dexmethylphenidate hydrochloride

Inactive ingredients: ammonio methacrylate copolymer, FD&C Blue #2 (5 mg, 15 mg, 25 mg, 35 mg, and 40 mg strengths), FDA/E172 yellow iron oxide (10 mg, 15 mg, 30 mg, 35 mg, and 40 mg strengths), gelatin, ink Tan SW-8010, methacrylic acid copolymer, polyethylene glycol, sugar spheres, talc, titanium dioxide, and triethyl citrate.

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