

MEDICATION GUIDE

Methylphenidate HCl Extended-Release Capsules CD CII

Read the Medication Guide that comes with Methylphenidate HCl Extended-Release Capsules CD 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 Methylphenidate HCl Extended-Release Capsules CD.

What is the most important information I should know about Methylphenidate HCl Extended-Release Capsules CD?

The following have been reported with use of methylphenidate HCl, USP 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 Methylphenidate HCl Extended-Release Capsules CD.

Your doctor should check your or your child's blood pressure and heart rate regularly during treatment with Methylphenidate HCl Extended-Release Capsules CD.

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 Methylphenidate HCl Extended-Release Capsules CD.

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 Methylphenidate HCl Extended-Release Capsules CD, 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 Methylphenidate HCl Extended-Release Capsules CD.**

What Is Methylphenidate HCl Extended-Release Capsules CD?

Methylphenidate HCl Extended-Release Capsules CD is a central nervous system stimulant prescription medicine. **It is used for the treatment of Attention-Deficit Hyperactivity Disorder (ADHD).**

Methylphenidate HCl Extended-Release Capsules CD may help increase attention and decrease impulsiveness and hyperactivity in patients with ADHD.

Methylphenidate HCl Extended-Release Capsules CD should be used as a part of a total treatment program for ADHD that may include counseling or other therapies.

Methylphenidate HCl Extended-Release Capsules CD is a federally controlled substance (CII) because it can be abused or lead to dependence. Keep Methylphenidate HCl Extended-Release Capsules CD in a safe place to prevent misuse and abuse. Selling or giving away Methylphenidate HCl Extended-Release Capsules CD 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 Methylphenidate HCl Extended-Release Capsules CD?

Methylphenidate HCl Extended-Release Capsules CD 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.
- have severe high blood pressure or a heart problem
- have hyperthyroidism
- are taking or have taken within the past 14 days an antidepressant medicine called a monoamine oxidase inhibitor or MAOI.
- are allergic to anything in Methylphenidate HCl Extended-Release Capsules CD. See the end of this Medication Guide for a complete list of ingredients.

Methylphenidate HCl Extended-Release Capsules CD should not be used in children less than 6 years old because it has not been studied in this age group.

Methylphenidate HCl Extended-Release Capsules CD may not be right for you or your child. Before starting Methylphenidate HCl Extended-Release Capsules CD 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 problem in fingers and toes

Tell your doctor if you or your child is pregnant, planning to become pregnant, or breastfeeding.

Can Methylphenidate HCl Extended-Release Capsules CD 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. Methylphenidate HCl Extended-Release Capsules CD and some medicines may interact with each other and cause serious side effects. Sometimes the doses of other medicines will need to be adjusted

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while taking Methylphenidate HCl Extended-Release Capsules CD.

Your doctor will decide whether Methylphenidate HCl Extended-Release Capsules CD 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 Methylphenidate HCl Extended-Release Capsules CD without talking to your doctor first.

How should Methylphenidate HCl Extended-Release Capsules CD be taken?

- **Take Methylphenidate HCl Extended-Release Capsules CD exactly as prescribed.** Your doctor may adjust the dose until it is right for you or your child.
- Take Methylphenidate HCl Extended-Release Capsules CD once each day in the morning before breakfast. Methylphenidate HCl Extended-Release Capsules CD is an extended release capsule. It releases medicine into your body throughout the day.
- Methylphenidate HCl Extended-Release Capsules CD can be taken with or without food.
- Swallow Methylphenidate HCl Extended-Release Capsules CD capsules whole with water or other liquids. If you cannot swallow the capsule, open it and sprinkle the medicine over a spoonful of applesauce. Swallow the applesauce and medicine mixture without chewing. Follow with a drink of water or other liquid. **Never chew or crush the capsule or the medicine inside the capsule.**
- Methylphenidate HCl Extended-Release Capsules CD should not be taken with alcohol. This may result in a more rapid release of the dose of Methylphenidate HCl Extended-Release Capsules CD.
- From time to time, your doctor may stop Methylphenidate HCl Extended-Release Capsules CD treatment for a while to check ADHD symptoms.
- Your doctor may do regular checks of the blood, heart, and blood pressure while taking Methylphenidate HCl Extended-Release Capsules CD. Children should have their height and weight checked often while taking Methylphenidate HCl Extended-Release Capsules CD. Methylphenidate HCl Extended-Release Capsules CD treatment may be stopped if a problem is found during these check-ups.
- **If you or your child takes too much Methylphenidate HCl Extended-Release Capsules CD or overdoses, call your doctor or poison control center right away, or get emergency treatment.**

What are possible side effects of Methylphenidate HCl Extended-Release Capsules CD?

See “**What is the most important information I should know about Methylphenidate HCl Extended-Release Capsules CD?**” 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
- 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:

- headache
- decreased appetite
- stomach ache
- nervousness
- trouble sleeping
- dizziness

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.

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 Methylphenidate HCl Extended-Release Capsules CD?

- Store Methylphenidate HCl Extended-Release Capsules CD in a safe place at room temperature, 59 to 86° F (15 to 30° C). Protect from moisture.
- **Keep Methylphenidate HCl Extended-Release Capsules CD and all medicines out of the reach of children.**

General information about Methylphenidate HCl Extended-Release Capsules CD

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Methylphenidate HCl Extended-Release Capsules CD for a condition for which it was not prescribed. Do not give Methylphenidate HCl Extended-Release Capsules CD 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 Methylphenidate HCl Extended-Release Capsules CD. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about Methylphenidate HCl Extended-Release Capsules CD that was written for healthcare professionals. For more information about Methylphenidate HCl Extended-Release Capsules CD call 1-844-834-0530.

What are the ingredients in Methylphenidate HCl Extended-Release Capsules CD?

Active Ingredient: methylphenidate HCl

Inactive Ingredients: sugar spheres, povidone, hydroxypropylmethylcellulose and polyethylene glycol, ethylcellulose aqueous dispersion, dibutyl sebacate, gelatin, and titanium dioxide.

The individual capsules contain the following coloring agents:

10 mg capsules: FD&C Blue No. 2, FDA/E172 Yellow Iron Oxide

20 mg capsules: FD&C Blue No. 2

30 mg capsules: FD&C Blue No. 2, FDA/E172 Red Iron Oxide

40 mg capsules: FDA/E172 Yellow Iron Oxide

50 mg capsules: FD&C Blue No. 2, FDA/E172 Red Iron Oxide

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

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