

MEDICATION GUIDE
METADATE CD®
(methylphenidate HCl, USP) Extended-Release Capsules CII

Read the Medication Guide that comes with METADATE 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 METADATE CD.

What is the most important information I should know about Metadate 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 METADATE CD.

Your doctor should check your or your child's blood pressure and heart rate regularly during treatment with METADATE 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 METADATE 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 METADATE CD, especially seeing or hearing things that are not real, believing things that are not real, or are suspicious.

What Is METADATE CD?

METADATE CD is a central nervous system stimulant prescription medicine. It is used for the treatment of Attention-Deficit Hyperactivity Disorder (ADHD).

METADATE CD may help increase attention and decrease impulsiveness and hyperactivity in patients with ADHD.

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

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

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

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

METADATE CD may not be right for you or your child. Before starting METADATE 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)

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

Can METADATE 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. METADATE 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 while taking METADATE CD.

Your doctor will decide whether METADATE 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 METADATE CD without talking to your doctor first.

How should METADATE CD be taken?

- **Take METADATE CD exactly as prescribed.** Your doctor may adjust the dose until it is right for you or your child.
- Take METADATE CD once each day in the morning before breakfast. METADATE CD is an extended release capsule. It releases medicine into your body throughout the day.
- METADATE CD can be taken with or without food.
- Swallow METADATE 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.**
- From time to time, your doctor may stop METADATE CD treatment for a while to check ADHD symptoms.
- Your doctor may do regular checks of the blood, heart, and blood pressure while taking METADATE CD. Children should have their height and weight checked often while taking METADATE CD. METADATE CD treatment may be stopped if a problem is found during these check-ups.
- **If you or your child takes too much METADATE CD or overdoses, call your doctor or poison control center right away, or get emergency treatment.**

What are possible side effects of METADATE CD?

See “What is the most important information I should know about METADATE 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

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 METADATE CD?

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

General information about METADATE CD

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use METADATE CD for a condition for which

it was not prescribed. Do not give METADATE 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 METADATE CD. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about METADATE CD that was written for healthcare professionals. For more information about METADATE CD call 1-866-822-0068.

What are the ingredients in METADATE 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.



Marketed by UCB, Inc.
Smyrna, GA 30080

Manufactured by UCB Manufacturing, Inc.
Rochester, NY 14623

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2E 06/2009