

MEDICATION GUIDE
METADATE® (MET-uh-date) ER
(methylphenidate HCl extended-release tablets, USP) Tablets CII

Read the Medication Guide that comes with METADATE ER 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 ER.

What is the most important information I should know about METADATE ER?

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 METADATE ER.

Your doctor should check your or your child's blood pressure and heart rate regularly during treatment with METADATE ER.

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 ER.

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 ER, 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 the fingers and 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 METADATE ER.**

What Is METADATE ER?

METADATE ER is a central nervous system stimulant prescription medicine. **It is used for the treatment of Attention-Deficit Hyperactivity Disorder (ADHD).** METADATE ER may help increase attention and decrease impulsiveness and hyperactivity in patients with ADHD.

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

METADATE ER is also used in the treatment of a sleep disorder called narcolepsy.

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

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

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

METADATE ER may not be right for you or your child. Before starting METADATE ER 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 breastfeeding.

Can METADATE ER be taken with other medicines?

Tell your doctor about all of the medicines that you or your child takes including prescription and nonprescription medicines, vitamins, and herbal supplements. METADATE ER 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 ER.

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

How should METADATE ER be taken?

- **Take METADATE ER exactly as prescribed.** Your doctor may adjust the dose until it is right for you or your child.
- Take METADATE ER 30 to 45 minutes before a meal. The effect of a dose of METADATE ER usually lasts about 8 hours.
- **Do not chew or crush METADATE ER tablets.** Swallow METADATE ER tablets whole with water or other liquids. Tell your doctor if you or your child cannot swallow METADATE ER whole. A different medicine may need to be prescribed.
- From time to time, your doctor may stop METADATE ER treatment for a while to check ADHD symptoms.
- Your doctor may do regular checks of the blood, heart, and blood pressure while taking METADATE ER. Children

should have their height and weight checked often while taking METADATE ER. METADATE ER treatment may be stopped if a problem is found during these check-ups.

- **If you or your child takes too much METADATE ER or overdoses, call your doctor or poison control center right away, or get emergency treatment.**

What are possible side effects of METADATE ER?

See “**What is the most important information I should know about METADATE ER?**” 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
- nausea

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 ER?

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

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

Manufactured for
Upstate Pharma, LLC
Smyrna, GA 30080

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General information about METADATE ER

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use METADATE ER for a condition for which it was not prescribed. Do not give METADATE ER to other people, even if they have the same condition. It may harm them and it is against the law.

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This Medication Guide summarizes the most important information about METADATE ER. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about METADATE ER that was written for healthcare professionals. For more information about METADATE ER call 1-844-599-2273.

What are the ingredients in METADATE ER?

Active Ingredient: methylphenidate HCl, USP

Inactive Ingredients: cetyl alcohol, ethylcellulose, anhydrous lactose and magnesium stearate.