

MEDICATION GUIDE
METADATE CD® (meh-tuh-dayt CD®)
(methylphenidate)
extended-release capsules, CII

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

METADATE CD may cause serious side effects, including:

- **Abuse, misuse, and addiction.** METADATE CD has a high chance for abuse and misuse and may lead to substance use problems, including addiction. Misuse and abuse of METADATE CD, other methylphenidate containing medicines, and amphetamine containing medicines, can lead to overdose and death. The risk of overdose and death is increased with higher doses of METADATE CD or when it is used in ways that are not approved, such as snorting or injection.
 - Your healthcare provider should check your child's risk for abuse, misuse, and addiction before starting treatment with METADATE CD and will monitor your child during treatment.
 - METADATE CD may lead to physical dependence after prolonged use, even if taken as directed by your healthcare provider.
 - Do not give METADATE CD to anyone else. See **“What is METADATE CD?”** for more information.

Keep METADATE CD in a safe place and properly dispose of any unused medicine. See **“How should I store METADATE CD?”** for more information. Tell your healthcare provider if your child has ever abused or been dependent on alcohol, prescription medicines, or street drugs.

- **Risks for people with serious heart disease.** Sudden death has happened in people who have heart defects or other serious heart disease. Your healthcare provider should check your child carefully for heart problems before starting treatment with METADATE CD. Tell your healthcare provider if your child has any heart problems, heart disease, or heart defects.

Call your healthcare provider or go to the nearest hospital emergency room right away if your child has any signs of heart problems such as chest pain, shortness of breath, or fainting during treatment with METADATE CD.

- **Increased blood pressure and heart rate.**

Your healthcare provider should check your child's blood pressure and heart rate regularly during treatment with METADATE CD.

- **Mental (psychiatric) problems, including:**

- new or worse behavior and thought problems
- new or worse bipolar illness
- new psychotic symptoms (such as hearing voices, or seeing or believing things that are not real) or new manic symptoms

Tell your healthcare provider about any mental problems your child has, or about a family history of, suicide, bipolar illness, or depression.

Call your healthcare provider right away if your child has any new or worsening mental symptoms or problems during treatment with METADATE CD, especially hearing voices, seeing or believing things that are not real, or new manic symptoms.

What is METADATE CD?

METADATE CD is a prescription medicine used for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in children 6 to 15 years of age. METADATE CD may help increase attention and decrease impulsiveness and hyperactivity in people with ADHD.

It is not known if METADATE CD is safe and effective for use in children younger than 6 years of age or older than 15 years of age.

METADATE CD is a federally controlled substance (CII) because it contains methylphenidate that can be a target for people who abuse prescription medicines or street drugs. Keep METADATE CD in a safe place to protect it from theft. Never give your METADATE CD to anyone else, because it may cause death or harm them. Selling or giving away METADATE CD may harm others and is against the law.

Who should not take METADATE CD?

Your child should not take METADATE CD if your child:

- is allergic to methylphenidate hydrochloride or any of the ingredients in METADATE CD. See the end of this Medication Guide for a complete list of ingredients in METADATE CD.
- has a rare inherited problem with the breaking down, absorbing, and processing of certain types of sugar in the body. METADATE CD contains a type of sugar called sucrose.
- is taking, or has stopped taking within the past 14 days, a medicine called a monoamine oxidase inhibitor (MAOI).

Before starting METADATE CD tell your healthcare provider about all your child's medical conditions, including: if your child:

- has heart problems, heart disease, heart defects, or high blood pressure
- has mental problems including psychosis, mania, bipolar illness, or depression or has a family history of suicide, bipolar illness, or depression
- has circulation problems in fingers and toes
- have eye problems, including increased pressure in your eye, glaucoma, or problems with your close-up vision (farsightedness)
- have or had repeated movements or sounds (tics) or Tourette's syndrome, or have a family history of tics or Tourette's syndrome
- is pregnant or plan to become pregnant. It is not known if METADATE CD will harm the unborn baby.
 - There is a pregnancy registry for females who are exposed to METADATE CD during pregnancy. The purpose of the registry is to collect information about the health of females exposed to METADATE CD and their baby. If you or your child becomes pregnant during treatment with METADATE CD, talk to your healthcare provider about registering with the National Pregnancy Registry for Psychostimulants at 1-866-961-2388.
- is breastfeeding or plan to breastfeed. METADATE CD passes into breast milk. Talk to your healthcare provider about the best way to feed the baby during treatment with METADATE CD.

Tell your healthcare provider about all the medicines that your child takes, including prescription and over-the-counter 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 changed during treatment with METADATE CD. Your healthcare provider will decide whether METADATE CD can be taken with other medicines.

Especially tell your healthcare provider if your child takes a medicine used to treat depression called a monoamine oxidase inhibitor (MAOI). Know the medicines that your child takes. Keep a list of the medicines with you to show your healthcare provider and pharmacist. **Your child should not start taking any new medicines during treatment with METADATE CD without talking to your healthcare provider first.**

How should METADATE CD be taken?

- Take METADATE CD exactly as prescribed by your healthcare provider.
- Your healthcare provider may change the dose if needed.
- Take METADATE CD 1 time each day in the morning before breakfast.
- Swallow METADATE CD capsules whole with water or other liquids.
- If METADATE CD capsules cannot be swallowed whole, the capsule may be opened and the contents sprinkled onto a tablespoonful of applesauce.
 - Follow with a drink of water or other liquid.
 - **Do not** chew the applesauce and medicine mixture.
 - Swallow all the applesauce and medicine mixture right away. Do not store the applesauce and medicine mixture.

If your child takes too much METADATE CD, call your healthcare provider or Poison Help line at 1-800-222-1222 or go to the nearest hospital emergency room right away.

What should be avoided during treatment with METADATE CD?

Avoid drinking alcohol during treatment with METADATE CD. This may cause a faster release of the METADATE CD medicine.

What are the possible side effects of METADATE CD?

METADATE CD may cause serious side effects, including:

- See “**What is the most important information I should know about METADATE CD?**”
- **Painful and prolonged erections (priapism).** Priapism has happened in males who take products that contain methylphenidate. **If your child develops priapism, get medical help right away.**
- **Circulation problems in fingers and toes (peripheral vasculopathy, including Raynaud’s phenomenon).** Signs and symptoms may include:
 - fingers or toes may feel numb, cool, painful
 - fingers or toes may change color from pale, to blue, to red

Tell your healthcare provider if your child has numbness, pain, skin color change, or sensitivity to temperature in the fingers or toes.

Call your healthcare provider right away if your child has any signs of unexplained wounds appearing on the fingers or toes during treatment with METADATE CD.

- **Slowing of growth (height and weight) in children.** Children should have their height and weight checked often during treatment with METADATE CD. METADATE CD treatment may be stopped if your child is not growing or gaining weight.
- **Eye problems (increased pressure in the eye and glaucoma).** Call your healthcare provider right away if you or your child develop changes in your vision or eye pain, swelling, or redness.
- **New or worsening tics or worsening Tourette’s syndrome.** Tell your healthcare provider if you or your child get any new or worsening tics or worsening Tourette’s syndrome during treatment with METADATE CD.

The most common side effects of METADATE CD include anorexia and trouble sleeping.

These are not all the possible side effects of METADATE CD.

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 at room temperature between 68°F to 77°F (20°C to 25°C).
- Store METADATE CD in a safe place, like a locked cabinet. Protect from light and moisture.
- Dispose of remaining, unused, or expired METADATE CD by a medicine take-back program at a U.S. Drug Enforcement Administration (DEA) authorized collection site. If no take-back program or DEA authorized collector is available, mix METADATE CD 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 METADATE CD in the household trash. Visit www.fda.gov/drugdisposal for additional information on disposal of unused medicines.

Keep METADATE CD and all medicines out of the reach of children

General information about the safe and effective use of 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 symptoms. It may harm them and it is against the law. You can ask your healthcare provider or pharmacist for information about METADATE CD that is written for healthcare professionals.

What are the ingredients in METADATE CD?

Active Ingredient: methylphenidate hydrochloride

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

Distributed by:
Aytu BioPharma
Denver, CO 80237

METADATE CD is a registered trademark of the Lannett Company, Inc.

For more information about METADATE CD call 1-855-298-8246.

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

Revised: 10/2023

N01421