

MEDICATION GUIDE

Methylphenidate hydrochloride tablets, USP

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What is the most important information I should know about methylphenidate hydrochloride tablets?

Methylphenidate hydrochloride is a federal controlled substance (CII) because it can be abused or lead to dependence. Keep methylphenidate hydrochloride tablets in a safe place to prevent misuse and abuse. Selling or giving away methylphenidate hydrochloride tablets 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 methylphenidate hydrochloride tablets.

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

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 hydrochloride tablets.

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 methylphenidate hydrochloride tablets, especially seeing or hearing things that are not real, believing things that are not real, or are suspicious.

What are methylphenidate hydrochloride tablets?

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

It is not known if methylphenidate hydrochloride tablets are safe and effective in children under 6 years of age.

Who should not take methylphenidate hydrochloride tablets?

Methylphenidate hydrochloride tablets should not be taken if you or your child:

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

Methylphenidate hydrochloride tablets may not be right for you or your child. Before starting methylphenidate hydrochloride tablets, 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 methylphenidate hydrochloride tablets will harm your unborn baby.
 - There is a pregnancy registry for females who are exposed to ADHD medications, including methylphenidate hydrochloride, during pregnancy. The purpose of the registry is to collect information about the health of females exposed to methylphenidate hydrochloride and their baby. If you or your child becomes pregnant during treatment with methylphenidate hydrochloride, 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, methylphenidate hydrochloride passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with methylphenidate hydrochloride.

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. Methylphenidate hydrochloride tablets 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 methylphenidate hydrochloride tablets.

Your doctor will decide whether methylphenidate hydrochloride tablets 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 methylphenidate hydrochloride tablets 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 methylphenidate hydrochloride tablets without talking to your doctor first.

How should methylphenidate hydrochloride tablets be taken?

- Take methylphenidate hydrochloride tablets exactly as prescribed. Your doctor may adjust the dose until it is right for you or your child.
- Methylphenidate hydrochloride tablets is usually taken 2 to 3 times a day.
- Take methylphenidate hydrochloride tablets 30 to 45 minutes before a meal.
- From time-to-time, your doctor may stop methylphenidate hydrochloride tablets treatment for a while to check ADHD symptoms.
- Your doctor may do regular checks of the blood, heart, and blood pressure while taking methylphenidate hydrochloride tablets.
- Children should have their height and weight checked often while taking methylphenidate hydrochloride tablets. Methylphenidate hydrochloride tablets 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 methylphenidate hydrochloride tablets?

Methylphenidate hydrochloride tablets may cause serious side effects, including:

- See “**What is the most important information I should know about methylphenidate hydrochloride tablets?**” 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 methylphenidate hydrochloride tablets.**
- **Slowing of growth (height and weight) in children**

Common side effects include:

- fast heart beat
- abnormal heartbeat (palpitations)
- headache
- trouble sleeping
- nervousness
- sweating a lot
- decreased appetite
- dry mouth
- nausea
- stomach 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 methylphenidate hydrochloride tablets?

- Store methylphenidate hydrochloride tablets in a safe place and in a tightly closed container at room temperature between 68°F to 77°F (20°C to 25°C).
- Protect from light.
- Dispose of remaining, unused, or expired methylphenidate hydrochloride tablets 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 methylphenidate hydrochloride tablets 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) methylphenidate hydrochloride tablets in the household trash.
- **Keep methylphenidate hydrochloride tablets and all medicines out of the reach of children.**

General information about the safe and effective use of methylphenidate hydrochloride tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. You can ask your pharmacist or doctor for information about methylphenidate hydrochloride tablets that is written for healthcare professionals. Do not use methylphenidate hydrochloride tablets for a condition for which it was not prescribed. Do not give methylphenidate hydrochloride tablets 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 methylphenidate hydrochloride tablets?

Active Ingredient: methylphenidate HCl.

Inactive Ingredients: Methylphenidate hydrochloride tablets, USP contain inactive ingredients: compressible sugar, colloidal silicon dioxide, D&C yellow no. 10 (5 mg and 20 mg tablets), lactose monohydrate, magnesium stearate, and microcrystalline cellulose.

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Manufactured for:
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For more information and request for additional copies of the Medication Guide, call XLCare Pharmaceuticals, Inc. at 1-866-495-1995.

This Medication Guide has been approved by the U.S. Food and Drug Administration. Rev: 08/21