

MEDICATION GUIDE
Methylphenidate Hydrochloride Extended-Release Tablets
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What is the most important information I should know about Methylphenidate hydrochloride extended-release tablets?

Methylphenidate hydrochloride extended-release tablets is a federal controlled substance (CII) because it can be abused or lead to dependence. Keep Methylphenidate hydrochloride extended-release tablets in a safe place to prevent misuse and abuse. Selling or giving away Methylphenidate hydrochloride extended-release tablets may harm others and is against the law. Tell your doctor if you or your child have ever 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 extended-release tablets.

Your doctor should check you or your child's blood pressure and heart rate regularly during treatment with Methylphenidate hydrochloride extended-release 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 extended-release 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 extended-release tablets, especially seeing or hearing things that are not real, believing things that are not real, or are suspicious.

What is Methylphenidate hydrochloride extended-release tablets?

Methylphenidate hydrochloride extended-release tablet is a central nervous system (CNS) stimulant prescription medicine used for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in people 6 years of age and older. Methylphenidate hydrochloride extended-release tablets may help increase attention and decrease impulsiveness and hyperactivity in patients with ADHD.

Methylphenidate hydrochloride extended-release tablets are not recommended for use in children under 6 years of age with ADHD.

Methylphenidate hydrochloride extended-release tablets should be used as a part of a total treatment program for ADHD

that may include counseling or other therapies.

Methylphenidate hydrochloride extended-release tablets are also used in the treatment of a sleep disorder called narcolepsy.

Who should not take Methylphenidate hydrochloride extended-release tablets?

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

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

Methylphenidate hydrochloride extended-release tablets may not be right for you or your child. Before starting Methylphenidate hydrochloride extended-release tablets tell you 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 extended-release tablets will harm your unborn baby.
 - There is a pregnancy registry for females who are exposed to ADHD medications, including Methylphenidate hydrochloride extended-release tablets, during pregnancy. The purpose of the registry is to collect information about the health of females exposed to Methylphenidate hydrochloride extended-release tablets and their baby. If you or your child becomes pregnant during treatment with Methylphenidate hydrochloride extended-release tablets 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/adhdmedications/>.
- 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 extended-release tablets.

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 extended-release 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 extended-release tablets.

Your doctor will decide whether Methylphenidate hydrochloride extended-release 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.

Do not start any new medicine while taking Methylphenidate hydrochloride extended-release tablets without talking to your doctor first.

How should Methylphenidate hydrochloride extended-release tablets be taken?

- Take Methylphenidate hydrochloride extended-release tablets exactly as prescribed. Your doctor may adjust the dose until it is right for you or your child.
- Take Methylphenidate hydrochloride extended-release tablets 30 to 45 minutes before a meal. The effect of a dose of Methylphenidate hydrochloride extended-release tablets usually lasts about 8 hours.
- **Do not chew or crush Methylphenidate hydrochloride extended-release tablets.** Swallow Methylphenidate hydrochloride extended-release tablets whole with water or other liquids. Tell your doctor if you or your child cannot swallow Methylphenidate hydrochloride extended-release tablets whole. A different medicine may need to be prescribed.
- From time to time, your doctor may stop Methylphenidate hydrochloride extended-release 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 extended-release tablets.
- Children should have their height and weight checked often while taking Methylphenidate hydrochloride extended-release tablets. Methylphenidate hydrochloride extended-release 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 extended-release tablets?

Methylphenidate hydrochloride extended-release tablets may cause serious side effects, including:

What are possible side effects of Methylphenidate hydrochloride extended-release tablets?

- See “What is the most important information I should know about Methylphenidate hydrochloride extended-release 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 extended-release 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 extended-release tablets?

- Store Methylphenidate hydrochloride extended-release 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 moisture.
- Dispose of remaining, unused, or expired Methylphenidate hydrochloride extended-release 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 extended-release 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 extended-release tablets in the household trash.
- **Keep Methylphenidate hydrochloride extended-release tablets and all medicines out of the reach of children.**

General information about the safe and effective use of Methylphenidate hydrochloride extended-release 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 extended-release tablets that is written for healthcare professionals. Do not use Methylphenidate hydrochloride extended-release tablets for a condition for which it was not prescribed. Do not give Methylphenidate hydrochloride extended-release tablets to other people, even if they have the same symptoms. It may harm them and it is against the law.

What are the ingredients in Methylphenidate hydrochloride extended-release tablets?

Active ingredient: methylphenidate hydrochloride

Inactive ingredients: hypromellose, microcrystalline cellulose, lactose monohydrate, colloidal silicon dioxide and magnesium stearate.

Manufactured by:

Granules Pharmaceuticals Inc.

Chantilly, VA 20151

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

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