

## MEDICATION GUIDE

### Methylphenidate Hydrochloride Tablets, USP, for oral use, CII

(METH-il-FEN-i-date HYE-droe-KLOR-ide)

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

#### Methylphenidate hydrochloride tablets may cause serious side effects, including:

- **Abuse, misuse, and addiction.** Methylphenidate hydrochloride tablets have a high chance for abuse and misuse and may lead to substance use problems, including addiction. Misuse and abuse of methylphenidate hydrochloride tablets, 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 methylphenidate hydrochloride tablets or when it is used in ways that are not approved, such as snorting or injection.
  - Your healthcare provider should check you or your child’s risk for abuse, misuse, and addiction before starting treatment with methylphenidate hydrochloride tablets and will monitor you or your child during treatment.
  - Methylphenidate hydrochloride tablets may lead to physical dependence after prolonged use, even if taken as directed by your healthcare provider.
  - Do not give methylphenidate hydrochloride tablets to anyone else. See “**What are methylphenidate hydrochloride tablets?**” for more information.
  - Keep methylphenidate hydrochloride tablets in a safe place and properly dispose of any unused medicine. See “**How should I store methylphenidate hydrochloride tablets?**” for more information.
  - Tell your healthcare provider if you or your child have 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 you or your child carefully for heart problems before starting methylphenidate hydrochloride tablets.

Tell your healthcare provider if you or your child have any heart problems, heart disease, or heart defects.

**Call your healthcare provider or go to the nearest hospital emergency room 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.**

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

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

- **Mental (psychiatric) problems:**

**All Patients**

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

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

**Call your healthcare provider 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.**

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

#### **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 healthcare provider about all health conditions (or a family history of), including:**

- heart problems, heart disease, heart defects, or high blood pressure
- mental problems, including psychosis, mania, bipolar illness, or depression
- circulation problems in fingers or 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.

- if you are pregnant or plan to become pregnant. It is not known if methylphenidate hydrochloride tablets will harm your unborn baby.
  - If you or your child becomes pregnant during treatment with methylphenidate hydrochloride tablets, talk to your healthcare provider.
- 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 tablets.

**Tell your healthcare provider 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 healthcare provider will decide whether methylphenidate hydrochloride tablets can be taken with other medicines.

**Especially tell your healthcare provider 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 healthcare provider 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 healthcare provider first.**

**How should methylphenidate hydrochloride tablets be taken?**

- Take methylphenidate hydrochloride tablets exactly as prescribed. Your healthcare provider may adjust the dose until it is right for you or your child.
- Methylphenidate hydrochloride tablets are usually taken 2 to 3 times a day.

- Take methylphenidate hydrochloride tablets 30 to 45 minutes before a meal.
- Your healthcare provider 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. If you or your child take too many methylphenidate hydrochloride tablets, call your healthcare provider or Poison Help line at 1-800-222-1222 or go to the nearest hospital emergency room right away.

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

**Call your healthcare provider 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.** Children should have their height and weight checked often during treatment with methylphenidate hydrochloride tablets. Methylphenidate hydrochloride tablets 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 methylphenidate hydrochloride tablets.

**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 a U.S. Drug Enforcement Administration (DEA) authorized collection site. If no take-back program or DEA 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 methylphenidate hydrochloride tablets in the household trash. Visit [www.fda.gov/drugdisposal](http://www.fda.gov/drugdisposal) for additional information on disposal of unused medicines.
- **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 healthcare provider 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, USP

**Inactive ingredients:** hypromellose, lactose monohydrate, microcrystalline cellulose, polyethylene glycol 8000, stearic acid, ferric oxide yellow (5-mg and 20-mg tablets), and FD&C Blue# 2 (10-mg tablets).

Manufactured by:

Princeton Laboratories

Charlotte, NC 28206, USA

Distributed by:

Solco Healthcare US, LLC

Somerset, NJ 08873, USA

For more information and request for additional copies of the Medication Guide, call 1-866-257-2597.

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

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