MEDICATION GUIDE
Methylphenidate Hydrochloride Extended-Release Capsules
(METH-il-FEN-i-date HYE-droe-KLOR-ide)
for oral use, CII

What is the most important information I should know about methylphenidate hydrochloride extended-release capsules?

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

- **Abuse, misuse, and addiction.** Methylphenidate hydrochloride extended-release capsules have a high chance for abuse and misuse and may lead to substance use problems, including addiction. Misuse and abuse of methylphenidate hydrochloride extended-release capsules, 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 extended-release capsules or when it is used in ways that are not approved, such as snorting or injection.

o Your healthcare provider should check you or your child's risk for abuse, misuse, and addiction before starting treatment with methylphenidate hydrochloride extended-release capsules and will monitor you or your child during treatment.

o Methylphenidate hydrochloride extended-release capsules may lead to physical dependence after prolonged use, even if taken as directed by your healthcare provider.

o Do not give methylphenidate hydrochloride extended-release capsules to anyone else. See **"What are methylphenidate hydrochloride extended-release capsules?"** for more information.

o Keep methylphenidate hydrochloride extended-release capsules in a safe place and properly dispose of any unused medicine. See **"How should I store methylphenidate hydrochloride extended-release capsules?"** for more information.

o 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 extended-release capsules.
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 extended-release capsules.

- **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 extended-release capsules.

- **Mental (psychiatric) problems:**

All Patients

- o new or worse behavior and thought problems
- o new or worse bipolar illness
- o 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 extended-release capsules, especially seeing or hearing things that are not real, believing things that are not real, or are suspicious.

What are methylphenidate hydrochloride extended-release capsules?

Methylphenidate hydrochloride extended-release capsules are a central nervous system (CNS) stimulant prescription medicine. **It is used for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).** Methylphenidate hydrochloride extended-release capsules may help increase attention and decrease impulsiveness and hyperactivity in patients with ADHD.

Methylphenidate hydrochloride extended-release capsules should be used as a part of a total treatment program for ADHD that may include counseling or other therapies.

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

Methylphenidate hydrochloride extended-release capsule 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 methylphenidate hydrochloride extended-release capsules in a safe place to protect it from theft. Never give your methylphenidate hydrochloride extended-release capsules to anyone else because it may cause death or harm them. Selling or giving away methylphenidate hydrochloride extended-release capsules may harm others and is against the law.

Who should not take methylphenidate hydrochloride extended-release capsules?

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

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

Methylphenidate hydrochloride extended-release capsules may not be right for you or your child. Before starting methylphenidate hydrochloride extended-release capsules, 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 extended-release capsules will harm your unborn baby.

- 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 the baby during treatment with methylphenidate hydrochloride extended-release capsules.

Tell your healthcare provider about all of the medicines that you or your child take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Methylphenidate hydrochloride extended-release capsules 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 capsules.

Your healthcare provider will decide whether methylphenidate hydrochloride extended-release capsules 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)
- risperidone

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 extended-release capsules 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 extended-release capsules without talking to your healthcare provider first.

How should methylphenidate hydrochloride extended-release capsules be taken?

- Take methylphenidate hydrochloride extended-release capsules exactly as prescribed. Your healthcare provider may adjust the dose until it is right for you or your child.

- Take methylphenidate hydrochloride extended-release capsules once a day in the morning. Methylphenidate hydrochloride extended-release capsules are an extended-release capsule.

- **Do not chew or crush methylphenidate hydrochloride extended-release capsules or the medicine inside the capsule.** Swallow methylphenidate hydrochloride extended-release capsules whole with water or other liquids.

- If you cannot swallow the capsule whole, open it and sprinkle the medicine over a spoonful of applesauce. Swallow the applesauce and medicine mixture without chewing. Follow with a drink of water or other liquid.

- You should avoid drinking alcohol during treatment with methylphenidate hydrochloride extended-release capsules. This may cause a faster release of methylphenidate hydrochloride extended-release capsules.

Your healthcare provider may do regular checks of the blood, heart, and blood pressure while taking methylphenidate hydrochloride extended-release capsules. Children should have their height and weight checked often while taking

methylphenidate hydrochloride extended-release capsules. If you or your child take too much methylphenidate hydrochloride extended-release capsules, 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 possible side effects of methylphenidate hydrochloride extended-release capsules?

- see **"What is the most important information I should know about methylphenidate hydrochloride extended-release capsules?"** 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 extended-release capsules.

- **Slowing of growth (height and weight) in children.** Children should have their height and weight checked often during treatment with methylphenidate hydrochloride extended-release capsules. Methylphenidate hydrochloride extended-release capsules 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 extended-release capsules.

- Common side effects include:
  - fast heartbeat
  - abnormal heartbeat (palpitations)
  - trouble sleeping
  - nervousness
  - sweating a lot
  - decreased appetite
  - 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 capsules?

- Store methylphenidate hydrochloride extended-release capsules in a safe place and in a tightly closed container at room temperature, 68°F to 77°F (20°C to 25°C).

- Protect from moisture.

- Dispose of remaining, unused, or expired methylphenidate hydrochloride extended-release capsules 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 extended-release capsules 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 extended-release capsules in the household trash. Visit www.fda.gov/drugdisposal for additional information on disposal of unused medicines.

- **Keep methylphenidate hydrochloride extended-release capsules and all medicines out of the reach of children.**

General information about the safe and effective use of methylphenidate hydrochloride extended-release capsules

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 extended-release capsules that is written for healthcare professionals. Do not use methylphenidate hydrochloride extended-release capsules for a condition for which it was not prescribed. Do not give methylphenidate hydrochloride extended-release capsules 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 capsules?

Active ingredient: methylphenidate HCl

Inactive ingredients: Acetyltributyl citrate, cellaburate, corn starch, gelatin, hypromellose acetate succinate, polyethylene glycol, sucrose, talc, and titanium dioxide. The 10 mg, 30 mg, 40 mg, and 60 mg capsules contain FD & C Yellow #6. The 10 mg, 30 mg, and 60 mg capsules also contain FD&C Yellow #5. The 40 mg and 60 mg capsules contain D&C Yellow #10. In addition, capsule printing ink contains ammonium hydroxide, black iron oxide, propylene glycol, and shellac glaze.

Methylphenidate Hydrochloride Extended-Release Capsules contain FD&C Yellow #5 (tartrazine).

Manufactured by:
Granules Pharmaceuticals Inc.,
Chantilly, VA 20151

For more information, call 1-877-770-3183.

This Medication Guide has been approved by the U.S. Food and Drug Administration. Revised: 10/2025