MEDICATION GUIDE
Methylphenidate Hydrochloride
(meth" il fen' i date hye" droe klor' ide)
Chewable Tablets, CII

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

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

- **Abuse, misuse, and addiction.** Methylphenidate hydrochloride chewable tablets has a high chance for abuse and misuse and may lead to substance use problems, including addiction. Misuse and abuse of methylphenidate hydrochloride chewable 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 chewable 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 chewable tablets and will monitor you or your child during treatment.
  - Methylphenidate hydrochloride chewable tablets may lead to physical dependence after prolonged use, even if taken as directed by your healthcare provider.
  - Do not give methylphenidate hydrochloride chewable tablets to anyone else. See **"What are methylphenidate hydrochloride chewable tablets?"** for more information.
  - Keep methylphenidate hydrochloride chewable tablets in a safe place and properly dispose of any unused medicine. See **"How should I store methylphenidate hydrochloride chewable 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 and during treatment with methylphenidate hydrochloride chewable tablets. Tell your healthcare provider if you or your child have any heart problems, heart disease, or heart defects.

Call your healthcare provider right away or go to the nearest hospital emergency room right away if you or your child have any signs of heart problems, such as chest pain, shortness of breath, or fainting during treatment with methylphenidate hydrochloride chewable 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 chewable tablets.

- **Mental (psychiatric) problems, including:**
  - new or worse behavior or 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 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 during treatment with methylphenidate hydrochloride chewable tablets, especially hearing voices, seeing or believing things that are not real, or new manic symptoms.

What are methylphenidate hydrochloride chewable tablets?

Methylphenidate hydrochloride chewable tablets are 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 chewable tablets may help increase attention and decrease impulsiveness and hyperactivity in people with ADHD.
- a sleep disorder called narcolepsy.

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

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

Who should not take methylphenidate hydrochloride chewable tablets?

Do not take methylphenidate hydrochloride chewable tablets if you or your child:

- are allergic to methylphenidate or any of the ingredients in methylphenidate hydrochloride chewable tablets. See the end of this Medication Guide for a complete list of ingredients in methylphenidate hydrochloride chewable tablets.
- are taking or have stopped taking within the past 14 days, a medicine called a monoamine oxidase inhibitor (MAOI).
- have a condition called pheochromocytoma (a rare tumor that usually grows in the adrenal glands which are above your kidneys).

Before taking methylphenidate hydrochloride chewable tablets tell your healthcare provider about all of your or your child's medical conditions, including if you or your child:

- have heart problems, heart disease, heart defects, or high blood pressure
- have mental problems including psychosis, mania, bipolar illness, or depression, or have a family history of suicide, bipolar illness, or depression
- have 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
- have trouble swallowing
- have phenylketonuria (PKU). The artificial sweetener aspartame in methylphenidate hydrochloride chewable tablets contains phenylalanine, which can be harmful to people with PKU.
- are pregnant or plan to become pregnant. It is not known if methylphenidate hydrochloride chewable tablets will harm your unborn baby.
  - There is a pregnancy registry for women who are exposed to methylphenidate hydrochloride chewable tablets during pregnancy. The purpose of the registry is to collect information about the health of women exposed to methylphenidate hydrochloride chewable tablets and their baby. If you or your child becomes pregnant during treatment with methylphenidate hydrochloride chewable tablets, talk to your healthcare provider about registering with the National Pregnancy Registry for ADHD Medications at 1-866-961-2388 or visit online at www.womensmentalhealth.org/research/pregnancyregistry/adhd-medications/.
- are breastfeeding or plan to breastfeed. Methylphenidate hydrochloride passes into breast milk. Talk to your healthcare provider about the best way to feed the baby during treatment with methylphenidate hydrochloride chewable tablets.

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 chewable tablets 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 methylphenidate hydrochloride chewable tablets. Your healthcare provider will decide whether methylphenidate hydrochloride chewable tablets can be taken with other medicines.

Especially tell your healthcare provider if you or your child take an monoamine oxidase inhibitor (MAOI).

Know the medicines that you or your child take. Keep a list of your or your child's medicines with you to show your or your child's healthcare provider and pharmacist when you or your child get a new medicine. **Do not start any new medicine during treatment with methylphenidate hydrochloride chewable tablets without talking to your or your child's healthcare provider first.**

How should I take methylphenidate hydrochloride chewable tablets?

- **Take methylphenidate hydrochloride chewable tablets exactly as prescribed by your healthcare provider.** Your healthcare provider may change the dose if needed.
- **For children 6 years of age and older:**
  - Take methylphenidate hydrochloride chewable tablets 2 times a day, 30 to 45 minutes before breakfast and lunch.
- **For adults:**
  - Take methylphenidate hydrochloride chewable tablets 2 or 3 times a day, 30 to 45 minutes before a meal.
  - If you have trouble sleeping when methylphenidate hydrochloride chewable tablets is taken late in the day, take your last dose before 6 p.m.
- Chew methylphenidate hydrochloride chewable tablets well and swallow with at least 8 ounces (a full glass) of water or other liquid.
  - Do not swallow methylphenidate hydrochloride chewable tablets whole.
  - If you do not take enough liquid with methylphenidate hydrochloride chewable tablets, this can cause you to choke. Stop taking methylphenidate hydrochloride chewable tablets and get medical help right away if you or your child have chest pain, vomiting, trouble swallowing, or trouble breathing after taking methylphenidate hydrochloride chewable tablets.
- If you or your child takes too much methylphenidate hydrochloride chewable 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 chewable tablets?

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

- See **"What is the most important information I should know about methylphenidate hydrochloride chewable tablets?"**
- **Painful and prolonged erections (priapism).** Priapism that may require surgery has happened in males who take products that contain methylphenidate. **If you or 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, or 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 or if you or your child have any signs of unexplained wounds appearing on fingers or toes during treatment with methylphenidate hydrochloride chewable tablets.

- **Slowing of growth (height and weight) in children.** Children should have their height and weight checked often during treatment with methylphenidate hydrochloride chewable tablets. Your healthcare provider may stop your child's treatment with methylphenidate hydrochloride chewable tablets if your child is not growing or gaining weight as expected.
- **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 chewable tablets.

The most common side effects of methylphenidate hydrochloride chewable tablets include:

- increased heart rate
- irregular heartbeat (palpitations)
- headache
- trouble sleeping
- anxiety
- nervousness
- sweating
- weight loss
- decreased appetite
- dry mouth
- nausea
- stomach (abdominal) pain

These are not all possible side effects of methylphenidate hydrochloride chewable tablets.

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 chewable tablets?

- Store methylphenidate hydrochloride chewable tablets at room temperature, at 68° to 77°F (20° to 25°C).
- Store methylphenidate hydrochloride chewable tablets in a safe place, like a locked cabinet.
- Protect methylphenidate hydrochloride chewable tablets from moisture.
- Dispose of remaining, unused, or expired methylphenidate hydrochloride chewable 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 chewable 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 chewable tablets in the household trash. Visit www.fda.gov/drugdisposal for additional information on disposal of unused medicines.

Keep methylphenidate hydrochloride chewable tablets and all medicines out of the reach of children.

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

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use methylphenidate hydrochloride chewable tablets for a condition for which it was not prescribed. Do not give methylphenidate hydrochloride chewable tablets to other people, even if they have the same symptoms. It may harm them, and it is against the law. You can ask your pharmacist or healthcare provider for information about methylphenidate hydrochloride chewable tablets that is written for health professionals.

For more information, please contact Camber Pharmaceuticals, Inc. at 1-866-495-8330.

What are the ingredients in methylphenidate hydrochloride chewable tablets?

Active ingredient: methylphenidate hydrochloride, USP

Inactive ingredients: The inactive ingredients are aspartame, lactose anhydrous, microcrystalline cellulose, guar gum, grape flavor, pregelatinized starch, and stearic acid.

Manufactured by:
Ascent Pharmaceuticals, Inc.
Central Islip, NY 11722

Manufactured for:
Camber Pharmaceuticals, Inc.
Piscataway, NJ 08854

This Medication Guide has been approved by the U.S. Food and Drug Administration. Rev: 09/2026