MEDICATION GUIDE
Methylphenidate Hydrochloride
(meth" il fen' i date hye" droe klor' ide)
Extended-Release Capsules CD
for oral use, CII

What is the most important information I should know about Methylphenidate HCl Extended-Release Capsules CD?

Methylphenidate HCl Extended-Release Capsules CD may cause serious side effects, including:

- **Abuse, misuse, and addiction.** Methylphenidate HCl Extended-Release Capsules CD has a high chance for abuse and misuse and may lead to substance use problems, including addiction. Misuse and abuse of Methylphenidate HCl Extended-Release Capsules CD, other methylphenidate medicines, and amphetamine medicines, can lead to overdose and death. The risk of overdose and death is increased with higher doses of Methylphenidate HCl Extended-Release Capsules CD or when it is used in ways that are not approved, such as snorting or injection.
  - Your healthcare provider should check your risk for abuse, misuse, and addiction before starting treatment with Methylphenidate HCl Extended-Release Capsules CD and will monitor you during treatment.
  - Methylphenidate HCl Extended-Release Capsules CD may lead to physical dependence after prolonged use, even if taken as directed by your healthcare provider.
  - **Do not** give Methylphenidate HCl Extended-Release Capsules CD to anyone else **because it may cause death or harm them**.
  - Keep Methylphenidate HCl Extended-Release Capsules CD in a safe place and properly dispose of any unused medicine. See "**How should I store Methylphenidate HCl Extended-Release Capsules CD?**" for more information.
  - Tell your healthcare provider if you 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 carefully for heart problems before starting Methylphenidate HCl Extended-Release Capsules CD. Tell your healthcare provider or go to the nearest hospital emergency room right away if you develop any signs of heart problems such as chest pain, shortness of breath, or fainting during treatment with Methylphenidate HCl Extended-Release Capsules CD.
- **Increased blood pressure and heart rate.** Your healthcare provider should check your blood pressure and heart rate regularly during treatment with Methylphenidate HCl Extended-Release Capsules CD.
- **Mental problems (psychiatric reactions), including:**
  - worsening behavior and thought problems in people with thought or psychotic disorders
  - manic episodes in people with bipolar disorder
  - new psychotic or manic symptoms in people without bipolar or psychotic disorders

Tell your healthcare provider right away if any mental symptoms or problems develop or worsen during treatment with Methylphenidate HCl Extended-Release Capsules CD, including:

- greatly increased energy
- racing thoughts
- unusually grand ideas
- talking more or faster than usual
- severe trouble sleeping
- reckless behavior
- excessive happiness or irritability
- seeing or hearing things that are not real (hallucinations)

See **"What are the possible side effects of Methylphenidate HCl Extended-Release Capsules CD?"** for more information about side effects.

What is Methylphenidate HCl Extended-Release Capsules CD?

Methylphenidate HCl Extended-Release Capsules CD is a central nervous system (CNS) stimulant prescription medicine used for the treatment of attention deficit hyperactivity disorder (ADHD) in children 6 years of age and older. Methylphenidate HCl Extended-Release Capsules CD may help increase attention and decrease impulsiveness and hyperactivity in children 6 years of age and older with ADHD.

Methylphenidate HCl Extended-Release Capsules CD is not recommended for use in children under 6 years of age.

Methylphenidate HCl Extended-Release Capsules CD is a federally controlled substance (CII) because it contains methylphenidate which can be abused and misused.

Who should not take Methylphenidate HCl Extended-Release Capsules CD?

Do not take Methylphenidate HCl Extended-Release Capsules CD if you:

- are allergic to methylphenidate hydrochloride or any of the ingredients in Methylphenidate HCl Extended-Release Capsules CD. See the end of this Medication Guide for a complete list of ingredients in Methylphenidate HCl Extended-Release Capsules CD.
- are taking or have stopped taking within the past 14 days a medicine called a monoamine oxidase inhibitor (MAOI).
- have an inherited problem with breaking down, absorbing, and processing certain types of sugar in the body. Methylphenidate HCl Extended-Release Capsules CD contains a type of sugar called sucrose.
- have a condition called pheochromocytoma or a history of pheochromocytoma.

Before taking Methylphenidate HCl Extended-Release Capsules CD, tell your healthcare provider about all of your medical conditions, including if you:

- have heart problems, heart disease, heart defects, or high blood pressure, or have a family history of sudden death or heart problems
- 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 uncontrolled movements or sounds (tics) or Tourette syndrome, or have a family history of tics or Tourette syndrome

- plan to have surgery. You should not take Methylphenidate HCl Extended-Release Capsules CD on the day of your surgery if a certain type of anesthetic is used because it may increase your chance for a sudden increase in blood pressure and heart rate during surgery.
- are pregnant or plan to become pregnant. It is not known if Methylphenidate HCl Extended-Release Capsules CD will harm the unborn baby.
  - o There is a pregnancy exposure registry for women who are exposed to Methylphenidate HCl Extended-Release Capsules CD during pregnancy. The purpose of the registry is to collect information about the health of women exposed to Methylphenidate HCl Extended-Release Capsules CD and their baby. If you become pregnant during treatment with Methylphenidate HCl Extended-Release Capsules CD, talk to your healthcare provider about registering with the National Pregnancy Registry for ADHD Medications at 1-866-961-2388 or visit online at https://womensmentalhealth.org/adhd-medications.
- are breastfeeding or plan to breastfeed. Methylphenidate HCl Extended-Release Capsules CD passes into breast milk. Talk to your healthcare provider about the best way to feed the baby during treatment with Methylphenidate HCl Extended-Release Capsules CD. If you breastfeed during treatment with Methylphenidate HCl Extended-Release Capsules CD, monitor your baby for agitation, poor sleeping patterns, changes in feeding, and reduced weight gain.

Tell your healthcare provider about all the medicines that you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Methylphenidate HCl Extended-Release Capsules CD and some medicines may interact with each other and cause serious side effects or affect the way Methylphenidate HCl Extended-Release Capsules CD or other medicines work. Sometimes the doses of other medicines will need to be changed during treatment with Methylphenidate HCl Extended-Release Capsules CD. Your healthcare provider will decide if Methylphenidate HCl Extended-Release Capsules CD can be taken with other medicines.

Especially tell your healthcare provider if you take:

- other CNS stimulant medicines
- blood pressure medicines (anti-hypertensives)
- risperidone

Know the medicines that you take. Keep a list of the medicines with you to show your healthcare provider and pharmacist when you get a new medicine. **Do not start any new medicine during treatment with Methylphenidate HCl Extended-Release Capsules CD without talking to your healthcare provider first.**

How should I take Methylphenidate HCl Extended-Release Capsules CD?

- Take Methylphenidate HCl Extended-Release Capsules CD exactly as prescribed by your healthcare provider.
- Your healthcare provider may change the dose or stop treatment with Methylphenidate HCl Extended-Release Capsules CD if you get certain side effects.
- Take Methylphenidate HCl Extended-Release Capsules CD 1 time each day in the morning before breakfast.
- Swallow Methylphenidate HCl Extended-Release Capsules CD capsules whole with liquids.
- **Do not** crush or chew the capsules.
- If you cannot swallow the capsules whole:

- open the capsule and sprinkle all of the contents onto a tablespoonful of applesauce
- swallow all the applesauce and medicine mixture right away without chewing and then drink liquids
- **do not** store the applesauce and medicine mixture for later use

- If you take too much Methylphenidate HCl Extended-Release Capsules CD, call your healthcare provider or Poison Help line at 1-800-222-1222 or go to the nearest hospital emergency room right away.

What should I avoid while taking Methylphenidate HCl Extended-Release Capsules CD?

Avoid drinking alcohol during treatment with Methylphenidate HCl Extended-Release Capsules CD. This can increase your risk for side effects and affect the way Methylphenidate HCl Extended-Release Capsules CD works.

What are the possible side effects of Methylphenidate HCl Extended-Release Capsules CD?

Methylphenidate HCl Extended-Release Capsules CD may cause serious side effects, including:

- See "**What is the most important information I should know about Methylphenidate HCl Extended-Release Capsules CD?**"
- **Painful and prolonged erections (priapism).** Priapism that may require surgery has happened in males who take medicines that contain methylphenidate. If you develop priapism, get medical help right away.
- **Circulation problems in fingers and toes (peripheral vasculopathy, including Raynaud's phenomenon).** Tell your healthcare provider if any of the following signs and symptoms of circulation problems develop during treatment:
  - fingers or toes feel numb, cool, painful
  - fingers or toes change color from pale, to blue, to red
  - sensitivity to temperature in fingers or toes

  Call your healthcare provider right away if any unexplained wounds appear on the fingers or toes during treatment with Methylphenidate HCl Extended-Release Capsules CD.

- **Slowing of growth (height and weight) in children.** Children should have their height and weight checked often during treatment with Methylphenidate HCl Extended-Release Capsules CD. Methylphenidate HCl Extended-Release Capsules CD treatment may be stopped in children who are not growing or gaining weight as expected.
- **Eye problems (increased pressure in the eye and glaucoma).** Tell your healthcare provider right away if you develop changes in your vision or eye pain, swelling, or redness.
- **New or worsening tics or worsening Tourette syndrome.** Tell your healthcare provider if you get any new or worsening tics or worsening Tourette syndrome during treatment with Methylphenidate HCl Extended-Release Capsules CD.

The most common side effects of Methylphenidate HCl Extended-Release Capsules CD, include headache, decreased appetite (anorexia), stomach (abdominal) pain, and trouble sleeping.

These are not all of the possible side effects of Methylphenidate HCl Extended-Release Capsules CD.

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 HCl Extended-Release Capsules CD?

- Store Methylphenidate HCl Extended-Release Capsules CD at room temperature between 68°F to 77°F (20°C to 25°C).
- Store Methylphenidate HCl Extended-Release Capsules CD in a safe place, like a locked cabinet.
- Dispose of remaining, unused, or expired Methylphenidate HCl Extended-Release Capsules CD 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 HCl Extended-Release Capsules CD 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 HCl Extended-Release Capsules CD in the household trash. Visit www.fda.gov/drugdisposal for additional information on disposal of unused medicines.

Keep Methylphenidate HCl Extended-Release Capsules CD and all medicines out of the reach of children.

General information about the safe and effective use of Methylphenidate HCl Extended-Release Capsules CD.

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

What are the ingredients in Methylphenidate HCl Extended-Release Capsules CD?

Active Ingredient: methylphenidate hydrochloride
Inactive Ingredients: dibutyl sebacate, ethylcellulose aqueous dispersion, gelatin, hydroxypropyl methylcellulose, polyethylene glycol, povidone, sugar spheres, and titanium dioxide.
The capsules also contain the following coloring agents: FD&C Blue No. 2 (10 mg, 20 mg, 30 mg, and 50 mg), FDA/E172 Yellow Iron Oxide (10 mg and 40 mg), and FDA/E172 Red Iron Oxide (30 mg and 50 mg).

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For more information about Methylphenidate HCl Extended-Release Capsules CD call 1-844-834-0530.

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

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