MEDICATION GUIDE
Methylphenidate hydrochloride extended-release tablets USP CII
(METH-il-FEN-i-date)

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

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

- **Abuse, misuse, and addiction.** Methylphenidate hydrochloride extended-release tablets 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 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 extended-release 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 extended-release tablets and will monitor you or your child during treatment.
  - Methylphenidate hydrochloride extended-release tablets may lead to physical dependence after prolonged use, even if taken as directed by your healthcare provider.
  - Do not give methylphenidate hydrochloride extended-release tablets to anyone else. See "**What are methylphenidate hydrochloride extended-release tablets?**" for more information.
  - Keep methylphenidate hydrochloride extended-release tablets in a safe place and properly dispose of any unused medicine. See "**How should I store methylphenidate hydrochloride extended-release 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 treatment with methylphenidate hydrochloride extended-release 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 have any signs of heart problems such as chest pain, shortness of breath, or fainting during treatment with methylphenidate hydrochloride extended-release tablets.

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

Your healthcare provider should check your or your child's blood pressure and heart rate regularly during treatment with methylphenidate hydrochloride extended-release 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 extended-release tablets, especially hearing voices, seeing or believing things that are not real, or new manic symptoms.

What are methylphenidate hydrochloride extended-release tablets?

Methylphenidate hydrochloride extended-release tablets are a central nervous system (CNS) stimulant prescription medicine used for the treatment of Attention Deficit and Hyperactivity Disorder (ADHD) in children 6 years of age and older and adults up to 65 years of age. Methylphenidate hydrochloride extended-release tablets may help increase attention and decrease impulsiveness and hyperactivity in people with ADHD. It is not known if methylphenidate hydrochloride extended-release tablets are safe and effective in children under 6 years of age. Methylphenidate hydrochloride extended-release tablets have not been studied in adults older than 65 years of age.

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

Do not take methylphenidate hydrochloride extended-release tablets if you or your child:

- are allergic to methylphenidate 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 stopped taking within the past 14 days, a medicine called monoamine oxidase inhibitor (MAOI)

Before taking methylphenidate hydrochloride extended-release 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 or have had seizures or have had an abnormal brain wave test (EEG)
- have circulation problems in fingers and toes
- have had a blockage or narrowing of the intestines
- 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
- are pregnant or plan to become pregnant. It is not known if methylphenidate hydrochloride extended-release tablets will harm the unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if methylphenidate hydrochloride extended-release tablets passes into the breastmilk. Talk to your healthcare provider about the best way to feed the baby during treatment with methylphenidate hydrochloride extended-release 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 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 changed during treatment with methylphenidate hydrochloride extended-release tablets. Your healthcare provider will decide whether methylphenidate hydrochloride extended-release tablets can be taken with other medicines.

Especially tell your healthcare provider if you or your child take:

- a medicine to treat blood pressure
- coumarin anticoagulants (a medicine that prevent blood clots, such as warfarin)
- a medicine to treat seizures
- a medicine to treat depression
- risperidone

Know the medicines that you or your child take. Keep a list of your or your child's medicines with you to show your healthcare provider and pharmacist when you or your child get a new medicine.

Do not start any new medicine during treatment with methylphenidate hydrochloride extended-release tablets without first talking to your healthcare provider.

How should methylphenidate hydrochloride extended-release tablets be taken?

- Take methylphenidate hydrochloride extended-release tablets exactly as prescribed by your or your child's healthcare provider.
- Your healthcare provider may change the dose or tell you to stop taking methylphenidate hydrochloride extended-release tablets if needed.
- Take methylphenidate hydrochloride extended-release tablets 1 time each day in the morning with or without food.
- Swallow methylphenidate hydrochloride extended-release tablets whole with water or other liquids. **Do not chew, crush, or divide the tablets.** Tell your healthcare provider if you or your child cannot swallow methylphenidate hydrochloride extended-release tablets whole. A different medicine may need to be prescribed.
- Methylphenidate hydrochloride extended-release tablets do not dissolve completely in the body after all the medicine has been released. You or your child may sometimes notice the empty tablet in a bowel movement. This is normal.
- Your healthcare provider may do blood tests during treatment with methylphenidate hydrochloride extended-release tablets to check your or your child's blood count.

If you or your child take too much methylphenidate hydrochloride extended-release 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 extended-release tablets?

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

- See **"What is the most important information I should know about methylphenidate hydrochloride extended-release tablets?"**
- **Seizures.** Your healthcare provider will stop treatment with methylphenidate hydrochloride extended-release tablets if you or your child have a seizure.
- **Painful and prolonged erections (priapism).** Priapism that may require surgery has happened in people who take products that contain methylphenidate. **If you or your child develop 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, painful
  - fingers or toes may change color from pale, to blue, to red

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

  Call your healthcare provider right away if you or your child have any signs of unexplained wounds appearing on fingers or toes during treatment with methylphenidate hydrochloride extended-release tablets.
- **Slowing of growth (height and weight) in children.** Children should have their height and weight checked often during treatment with methylphenidate hydrochloride extended-release tablets. Methylphenidate hydrochloride extended-release tablets treatment may be stopped 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 extended-release tablets.
- **Eyesight changes or blurred vision.**
- **Possible blockage of the intestine.** Because the methylphenidate hydrochloride extended-release tablets do not change in shape in the intestines (GI tract), methylphenidate hydrochloride extended-release tablets should not be taken by people with severe intestinal problems (pre-existing severe gastrointestinal narrowing).

The most common side effect of methylphenidate hydrochloride extended-release tablets in children is upper stomach-area (abdominal) pain.

The most common side effects of methylphenidate hydrochloride extended-release tablets in adults include:

- **decreased appetite**
- **anxiety**
- **headache**
- **dizziness**
- **dry mouth**
- **weight loss**
- **nausea**
- **irritability**
- **trouble sleeping**
- **increased sweating**

These are not all the possible side effects of methylphenidate hydrochloride extended-release tablets. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. You may also report side effects to Alora Pharmaceuticals at 1-800-541-4802.

How should I store methylphenidate hydrochloride extended-release tablets?

- Store methylphenidate hydrochloride extended-release tablets at room temperature between 59°F to 86°F (15°C to 30°C).
- Protect from moisture.
- Store methylphenidate hydrochloride extended-release tablets in a safe place, like a locked cabinet.
- Dispose of remaining, unused, or expired methylphenidate hydrochloride extended-release 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 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 methylphenidate hydrochloride extended-release tablets in the household trash. Visit www.fda.gov/drugdisposal for additional information on disposal of unused medicines.

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. 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 condition. It may harm them and it is against the law.

You can ask your healthcare provider or pharmacist for information about methylphenidate hydrochloride extended-release tablets that is written for healthcare professionals.

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

Active ingredient: methylphenidate hydrochloride

Inactive ingredients: black iron oxide, cellulose acetate, colloidal silicon dioxide, ferrosoferric oxide, hypromellose, lactose monohydrate, magnesium stearate, phosphoric acid, polyethylene glycol, polyethylene oxide, sodium chloride, succinic acid, titanium dioxide, triacetin. In addition,

27 mg tablets contain: FD&C Yellow #6 Aluminum Lake, FD&C Blue #2 Aluminum Lake, FD&C Red #40 Aluminum Lake

54 mg tablets contain: FD&C Yellow #6 Aluminum Lake, FD&C Red #40 Aluminum Lake, FD&C Blue #2 Aluminum Lake

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