

## **MEDICATION GUIDE**

**Methylphenidate hydrochloride extended-release tablets USP CII** 18-mg, 27-mg, 36-mg, 54-mg, 72-mg tablets (METH-il-FEN-i-date)

Read the Medication Guide that comes with methylphenidate hydrochloride extended-release tablets USP before you or your child starts taking it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your doctor about your or your child's treatment with methylphenidate hydrochloride extended-release tablets USP.

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

**The following have been reported with use of methylphenidate HCl and other stimulant medicines:**

**1. Heart-related problems:**

- **sudden death in patients who have heart problems or heart defects**
- **stroke and heart attack in adults**
- **increased blood pressure and heart rate**

Tell your doctor if you or your child has any heart problems, heart defects, high blood pressure, or a family history of these problems.

Your doctor should check you or your child carefully for heart problems before starting methylphenidate hydrochloride extended-release tablets.

Your doctor should check your or your child's blood pressure and heart rate regularly during treatment with methylphenidate hydrochloride extended-release tablets.

**Call your doctor 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 tablets.**

**2. Mental (Psychiatric) problems:**

**All Patients**

- **new or worse behavior and thought problems**
- **new or worse bipolar illness**
- **new or worse aggressive behavior or hostility**

**Children and Teenagers**

- **new psychotic symptoms (such as hearing voices, believing things that are not true, are suspicious) or new manic symptoms**

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

**Call your doctor right away if you or your child has any new or worsening mental symptoms or problems while taking methylphenidate hydrochloride extended-release tablets, especially seeing or hearing things that are not real, believing things that are not real, or are suspicious.**

### **3. Painful and prolonged erections (priapism)**

Painful and prolonged erections (priapism) have occurred with methylphenidate. If you or your child develop priapism, seek medical help right away. **Because of the potential for lasting damage, priapism should be evaluated by a doctor immediately.**

### **4. 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 doctor if you have or your child has numbness, pain, skin color change, or sensitivity to temperature in your fingers or toes.

**Call your doctor 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 tablets.**

### **What is methylphenidate hydrochloride extended-release tablets?**

**Methylphenidate hydrochloride extended-release tablets** are a central nervous system stimulant prescription medicine. **It is used for the treatment of attention deficit and hyperactivity disorder (ADHD).**

**Methylphenidate hydrochloride extended-release tablets** may help increase attention and decrease impulsiveness and hyperactivity in patients with ADHD.

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

**Methylphenidate hydrochloride extended-release tablets are a federally controlled substance (CII) because it can be abused or lead to dependence. Keep methylphenidate hydrochloride extended-release tablets in a safe place to prevent misuse and abuse. Selling or giving away methylphenidate hydrochloride extended-release tablets may harm others, and is against the law.**

Tell your doctor if you or your child has (or has a family history of) ever abused or been dependent on alcohol, prescription medicines, or street drugs.

### **Who should not take methylphenidate hydrochloride extended-release tablets?**

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

- is very anxious, tense, or agitated
- has an eye problem called glaucoma
- has tics or Tourette's syndrome, or a family history of Tourette's syndrome. Tics are hard-to-control repeated movements or sounds.
- is taking or has taken within the past 14 days an antidepressant medicine called a monoamine oxidase inhibitor or MAOI.
- is allergic to anything in methylphenidate hydrochloride extended-release tablets. See the end of this Medication Guide for a complete list of ingredients.

Methylphenidate hydrochloride extended-release tablets should not be used in children less than 6 years old because it has not been studied in this age group.

**Methylphenidate hydrochloride extended-release tablets may not be right for you or your child. Before starting methylphenidate hydrochloride extended-release tablets, tell your or your child's doctor about all health conditions (or a family history of) including:**

- heart problems, heart defects, or high blood pressure
- mental problems including psychosis, mania, bipolar illness, or depression
- tics or Tourette's syndrome

- seizures or have had an abnormal brain wave test (EEG)
- circulation problems in fingers and toes
- esophagus, stomach, or small or large intestine problems

Tell your doctor if you or your child is pregnant, planning to become pregnant, or breastfeeding.

### **Can methylphenidate hydrochloride extended-release tablets be taken with other medicines?**

**Tell your doctor about all of the medicines that you or your child takes including prescription and nonprescription 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 adjusted while taking methylphenidate hydrochloride extended-release tablets.

Your doctor will decide whether methylphenidate hydrochloride extended-release tablets can be taken with other medicines.

### **Especially tell your doctor if you or your child takes:**

- antidepressant medicines including MAOIs
- seizure medicines
- blood thinner medicines
- blood pressure medicines
- cold or allergy medicines that contain decongestants

Know the medicines that you or your child takes. Keep a list of your medicines with you to show your doctor and pharmacist.

**Do not start any new medicine while taking methylphenidate hydrochloride extended-release tablets without talking to your doctor first.**

### **How should methylphenidate hydrochloride extended-release tablets be taken?**

- **Take methylphenidate hydrochloride extended-release tablets exactly as prescribed.** Your doctor may adjust the dose until it is right for you or your child.
- **Do not chew, crush, or divide the tablets.** Swallow methylphenidate hydrochloride extended-release tablets whole with water or other liquids. Tell your doctor 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 can be taken with or without food.
- Take methylphenidate hydrochloride extended-release tablets once each day in the morning. Methylphenidate hydrochloride extended-release tablets are an extended-release tablet. It releases medication into your or your child's body throughout the day.
- The methylphenidate hydrochloride extended-release tablet does 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.
- From time to time, your doctor may stop methylphenidate hydrochloride extended-release tablets treatment for a while to check ADHD symptoms.
- Your doctor may do regular checks of the blood, heart, and blood pressure while taking methylphenidate hydrochloride extended-release tablets. Children should have their height and weight checked often while taking methylphenidate hydrochloride extended-release tablets. Methylphenidate hydrochloride extended-release tablets treatment may be stopped if a problem is found during these check-ups.
- **If you or your child takes too much methylphenidate hydrochloride extended-release tablets or overdoses, call your doctor or poison control center right away, or get emergency treatment.**

### **What are possible side effects of methylphenidate hydrochloride extended-release tablets?**

See "What is the most important information I should know about methylphenidate hydrochloride extended-release tablets?" for information on reported heart and mental problems.

**Other serious side effects include:**

- slowing of growth (height and weight) in children
- seizures, mainly in patients with a history of seizures
- eyesight changes or blurred vision
- blockage of the esophagus, stomach, small or large intestine in patients who already have a narrowing in any of these organs

**Common side effects include:**

- |                      |                |
|----------------------|----------------|
| • decreased appetite | • headache     |
| • dry mouth          | • nausea       |
| • trouble sleeping   | • anxiety      |
| • dizziness          | • weight loss  |
| • stomach ache       | • irritability |
| • increased sweating |                |

Stimulants may impair the ability of you or your child to operate potentially hazardous machinery or vehicles. You or your child should exercise caution until you or your child is reasonably certain that methylphenidate hydrochloride extended-release tablets does not adversely affect your or your child's ability to engage in such activities.

Talk to your doctor if you or your child has side effects that are bothersome or do not go away.

This is not a complete list of possible side effects. Ask your doctor or pharmacist for more information.

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 Trigen Laboratories, LLC at 1-770-509-4500.

**How should I store methylphenidate hydrochloride extended-release tablets?**

Store methylphenidate hydrochloride extended-release tablets USP in a safe place at room temperature, 59 to 86°F (15 to 30°C). Protect from moisture.

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

**General information about 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.

This Medication Guide summarizes the most important information about methylphenidate hydrochloride extended-release tablets. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about methylphenidate hydrochloride extended-release tablets that was written for healthcare professionals. For more information about methylphenidate hydrochloride extended-release tablets call 1-877-482-3788.

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

**Active Ingredient:** methylphenidate HCl

**Inactive Ingredients:** black iron oxide, cellulose acetate, colloidal silicon dioxide, ferrousferic 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

72 mg tablets contain: FD&C Blue #1 Aluminum Lake

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

Manufactured for:  
Trigen Laboratories, LLC  
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1-770-509-4500  
[www.trigenlab.com](http://www.trigenlab.com)



200206-03 Rev. 11/2021

**MEDICATION GUIDE**  
**Methylphenidate hydrochloride extended-release 45-mg & 63-mg tablets**  
**(METH-il-FEN-i-date)**  
**for oral use, CII**

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

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

- **Abuse and dependence.** Methylphenidate hydrochloride extended-release tablets, other methylphenidate containing medicines, and amphetamines have a high chance for abuse and can cause physical and psychological dependence. Your healthcare provider should check you or your child for signs of abuse and dependence before and during treatment with methylphenidate hydrochloride extended-release tablets.
  - Tell your healthcare provider if you or your child has ever abused or been dependent on alcohol, prescription medicines, or street drugs.
  - Your healthcare provider can tell you more about the differences between physical and psychological dependence and drug addiction.
- **Heart-related problems, including:**
  - sudden death, stroke, and heart attack in adults
  - sudden death in children who have heart related problems or defects
  - increased blood pressure and heart rate

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 defects, high blood pressure, or a family history of these problems.

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

**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.**

- **Mental (psychiatric) problems, including:**
  - new or worse behavior and 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 Hyperactivity Disorder (ADHD) in adults less than 65 years of age and children 6 years of age and older. 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 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 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.
- taking, or have stopped taking within the past 14 days, a medicine called a monoamine oxidase inhibitor (MAOI).

**Before taking methylphenidate hydrochloride extended-release tablets tell your healthcare provider about all your medical conditions, including if you or your child:**

- have heart problems, heart defects, or high blood pressure
- have mental problems including psychosis, mania, bipolar illness, or depression, or a family history of suicide, bipolar illness, or depression
- have circulation problems in fingers and toes
- are pregnant or plan to become pregnant. It is not known if methylphenidate hydrochloride extended-release tablets will harm the unborn baby.
  - **Pregnancy Exposure Registry:** There is a pregnancy registry for women who are exposed to methylphenidate hydrochloride extended-release tablets during pregnancy. The purpose of the registry is to collect information about the health of women exposed to methylphenidate hydrochloride extended-release tablets and their baby. If you or your child becomes pregnant during treatment with methylphenidate hydrochloride extended-release tablets, talk to your healthcare provider about registering with the National Pregnancy Registry for Psychostimulants at 1-866-961-2388.
- are breastfeeding or plan to breastfeed. Methylphenidate hydrochloride extended-release tablets passes into breast milk. 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:**

- blood pressure medicines (anti-hypertensive)
- risperidone

Know the medicines that you take or your child take. Keep a list of your medicines with you to show your healthcare provider and pharmacist. **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 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 tablet does 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 sometimes stop methylphenidate hydrochloride extended-release tablets treatment for a while to check ADHD symptoms.

If you or your child take too much methylphenidate hydrochloride extended-release tablets, call your healthcare provider or poison control center 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 can cause serious side effects, including:**

- See **"What is the most important information I should know about methylphenidate hydrochloride extended-release 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 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 numbness, pain, skin color change, or sensitivity to temperature in your 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 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.
- **Possible blockage of the intestine.** Because the methylphenidate hydrochloride extended-release tablet does not change in shape in the intestines (GI tract), methylphenidate hydrochloride extended-release tablets should not be taken by people with severe intestinal problems (preexisting severe gastrointestinal narrowing).

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

- |                               |                      |
|-------------------------------|----------------------|
| • decreased appetite          | • headache           |
| • dry mouth                   | • nausea             |
| • trouble sleeping (insomnia) | • anxiety            |
| • dizziness                   | • weight loss        |
| • irritability                | • increased sweating |

**The most common side effects of methylphenidate hydrochloride extended-release tablets in children 6 to 17 years of age was stomach pain.**

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.

**How should I store methylphenidate hydrochloride extended-release tablets?**

- Store methylphenidate hydrochloride extended-release tablets at room temperature between 68°F to 77°F (20°C to 25°C).
- Store methylphenidate hydrochloride extended-release tablets in a safe place, like a locked cabinet. Protect from light and moisture.
- Dispose of remaining, unused, or expired methylphenidate hydrochloride extended-release tablets by a medicine take-back program at authorized collection sites such as retail pharmacies, hospital or clinic pharmacies, and law enforcement locations. If no take-back program or 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.

**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 symptoms that you have. 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 was written for healthcare professionals.

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

**Active Ingredient:** methylphenidate hydrochloride

**Inactive Ingredients:** cellulose acetate, colloidal silicon dioxide, ferrousferic oxide, hypromellose, iron oxide black, lactose monohydrate, magnesium stearate, phosphoric acid, polyethylene glycol, polyethylene oxide, sodium chloride, succinic acid, titanium dioxide, and triacetin.

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

45 mg tablets contain: 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

63 mg tablets contain: iron oxide red, iron oxide yellow

72 mg tablets contain: FD&C Blue #1 Aluminum Lake

**Manufactured For:**

Trigen Laboratories, LLC

Alpharetta, GA 30005



For more information, go to [www.trigenlab.com](http://www.trigenlab.com) or call 1-800-444-5164  
200320-1

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

Revised: 06/2022