

MEDICATION GUIDE

Methylphenidate hydrochloride Extended-release Tablets, USP CII (meth ' il fen' i date hye" droe klor' ide)

Read the Medication Guide that comes with methylphenidate hydrochloride extended-release tablets 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.

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 is 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 is 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 is an extended-release tablet. It releases medication into your or your child's body throughout the day.
- The methylphenidate hydrochloride extended-release tablets 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 checkups.
- **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
- dry mouth
- trouble sleeping
- dizziness
- stomach ache
- increased sweating
- headache
- nausea
- anxiety
- weight loss
- irritability

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 Camber Pharmaceuticals Inc., at 1-866-495-8330.

How should I store methylphenidate hydrochloride extended-release tablets?

- Store methylphenidate hydrochloride extended-release tablets in a safe place at room temperature. Store at 20° to 25°C (68° to 77°F). 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 1-866-495-8330.

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

Active Ingredient: methylphenidate HCl.

Inactive Ingredients: Methylphenidate hydrochloride extended-release tablets contains the following inert ingredients and are common to all strengths: butylated hydroxytoluene, cellulose acetate, hypromellose, phosphoric acid, polyethylene glycol, polyethylene oxides, povidone, propylene glycol, sodium chloride, stearic acid, succinic acid, ferric oxide yellow, FD&C Red No 40 and titanium dioxide. The 18 mg tablet strength also contains iron oxide yellow and Polysorbate 80. The 27 mg tablet strength also contains iron oxide red. The 36 mg tablet strength also contains talc. The 54 mg tablet strength also contains iron oxide yellow, iron oxide red and talc.

Each tablet strength also contains black iron oxide, hypromellose and propylene glycol as imprinting ink.

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

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