

MEDICATION GUIDE

Methylphenidate Hydrochloride Oral Solution



5 mg/5 mL and 10 mg/5 mL

Read the Medication Guide that comes with methylphenidate hydrochloride oral solution 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 oral solution.

What is the most important information I should know about methylphenidate hydrochloride oral solution?

The following have been reported with use of methylphenidate HCl oral solution 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 have 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 oral solution.

Your doctor should check you or your child's blood pressure and heart rate regularly during treatment with methylphenidate hydrochloride oral solution.

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 oral solution.

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 have any new or worsening mental symptoms or problems while taking methylphenidate hydrochloride oral solution, especially seeing or hearing things that are not real, believing things that are not real, or are suspicious.

What is methylphenidate hydrochloride oral solution?

Methylphenidate hydrochloride oral solution is a central nervous system stimulant prescription medicine. Methylphenidate hydrochloride oral solution is a liquid form of medication that you take by mouth. It is used for the treatment of Attention-Deficit Hyperactivity Disorder (ADHD). Methylphenidate hydrochloride oral solution may help increase attention and decrease impulsiveness and hyperactivity in patients with ADHD.

Methylphenidate hydrochloride oral solution should be used as a part of a total treatment program for ADHD that may include counseling or other therapies.

Methylphenidate hydrochloride oral solution is also used in the treatment of a sleep disorder called narcolepsy.

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

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

Who should not take methylphenidate hydrochloride oral solution?

Methylphenidate hydrochloride oral solution should not be taken if you or your child:

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

Methylphenidate hydrochloride oral solution should not be used in children less than 6 years old because it has not been studied in this age group.

Methylphenidate hydrochloride oral solution may not be right for you or your child. Before starting methylphenidate hydrochloride oral solution tell your or your child's doctor about all health conditions (or a family history of) including:

- heart problems, heart defects, 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)

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

Can methylphenidate hydrochloride oral solution be taken with other medicines?

Tell your doctor about all of the medicines that you or your child take including prescription and nonprescription medicines, vitamins, and herbal supplements. Methylphenidate hydrochloride oral solution 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 oral solution.

Your doctor will decide whether methylphenidate hydrochloride oral solution can be taken with other medicines.

Especially tell your doctor if you or your child takes:

- anti-depression 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 oral solution without talking to your doctor first.

How should methylphenidate hydrochloride oral solution be taken?

- Take methylphenidate hydrochloride oral solution exactly as prescribed. Your doctor may adjust the dose until it is right for you or your child.
- Methylphenidate hydrochloride oral solution is usually taken 2 to 3 times a day.
- Take methylphenidate hydrochloride oral solution 30 to 45 minutes before meals.
- From time to time, your doctor may stop methylphenidate hydrochloride oral solution treatment for awhile to check ADHD symptoms.
- Your doctor may do regular checks of the blood, heart, and blood pressure while taking methylphenidate hydrochloride oral solution. Children should have their height and weight checked often while taking methylphenidate hydrochloride oral solution. Methylphenidate hydrochloride oral solution treatment may be stopped if a problem is found during these check-ups.
- If you or your child takes too much methylphenidate hydrochloride oral solution or overdoses, call your doctor or poison control center right away, or get emergency treatment.

What are possible side effects of methylphenidate hydrochloride oral solution?

See "What is the most important information I should know about methylphenidate hydrochloride oral solution?" 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

Common side effects include:

- nervousness
- stomach ache
- decreased appetite
- trouble sleeping
- fast heart beat
- dizziness
- headache
- nausea
- weight loss

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 also report side effects to FDA at 1-800-FDA-1088.

How should I store methylphenidate hydrochloride oral solution?

- Store methylphenidate hydrochloride oral solution in a safe place at room temperature, 68° to 77°F (20° to 25°C).
- Keep methylphenidate hydrochloride oral solution and all medicines out of the reach of children.

General information about methylphenidate hydrochloride oral solution

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use methylphenidate hydrochloride oral solution for a condition for which it was not prescribed. Do not give methylphenidate hydrochloride oral solution 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 oral solution. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about methylphenidate hydrochloride oral solution that was written for healthcare professionals.

For more information, please contact Tris Pharma Inc. at 732-940-0358.

What are the ingredients in methylphenidate hydrochloride oral solution?

Active Ingredient: methylphenidate hydrochloride USP

Inactive Ingredients: artificial grape flavor, glycerin, hydrochloric acid, polyethylene glycol 1450, and purified water.

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

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