

MEDICATION GUIDE
RITALIN® (rit-ah-lin)
(methylphenidate hydrochloride)
tablets CII

What is the most important information I should know about RITALIN?

RITALIN is a federal controlled substance (CII) because it can be abused or lead to dependence. Keep RITALIN in a safe place to prevent misuse and abuse. Selling or giving away RITALIN may harm others and is against the law.

Tell your doctor if you or your child have abused or been dependent on alcohol, prescription medicines, or street drugs.

The following have been reported with use of methylphenidate hydrochloride 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 RITALIN.

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

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 RITALIN.

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**
- **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 RITALIN, especially seeing or hearing things that are not real, believing things that are not real, or are suspicious.

What is RITALIN?

- RITALIN is a central nervous system (CNS) stimulant prescription medicine. **It is used for the treatment of Attention-Deficit Hyperactivity Disorder (ADHD).** RITALIN may help increase attention and decrease impulsiveness and hyperactivity in patients with ADHD.
- RITALIN should be used as a part of a total treatment program for ADHD that may include counseling or other therapies.
- RITALIN is also used in the treatment of a sleep disorder called narcolepsy.

It is not known if RITALIN is safe and effective in children under 6 years of age.

Who should not take RITALIN?

RITALIN should not be taken if you or your child:

- are allergic to methylphenidate hydrochloride, or any of the ingredients in RITALIN. See the end of this Medication Guide for a complete list of ingredients in RITALIN.
- are taking or have taken within the past 14 days an anti-depression medicine called a monoamine oxidase inhibitor or MAOI.

RITALIN may not be right for you or your child. Before starting RITALIN, 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
- circulation problems in fingers or toes

- if you are pregnant or plan to become pregnant. It is not known if RITALIN will harm your unborn baby. Talk to your doctor if you are pregnant or plan to become pregnant.
- if you are breastfeeding or plan to breastfeed. RITALIN passes into your breast milk. You and your doctor should decide if you will take RITALIN or breastfeed.

Tell your doctor about all of the medicines that you or your child takes including prescription and over-the-counter medicines, vitamins, and herbal supplements. RITALIN 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 RITALIN.

Your doctor will decide whether RITALIN can be taken with other medicines.

Especially tell your doctor if you or your child takes:

- anti-depression medicines including MAOIs
- blood pressure medicines (anti-hypertensive)

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

- You should not take RITALIN on the day of your operation if a certain type of anesthetic is used. This is because there is a chance of a sudden rise in blood pressure and heart rate during the operation.

Do not start any new medicine while taking RITALIN without talking to your doctor first.

How should RITALIN be taken?

- Take RITALIN exactly as prescribed. Your doctor may adjust the dose until it is right for you or your child.
- RITALIN is usually taken 2 to 3 times a day.
- Take RITALIN 30 to 45 minutes before a meal.
- From time to time, your doctor may stop RITALIN treatment for a while to check ADHD symptoms.
- Your doctor may do regular checks of the blood, heart, and blood pressure while taking RITALIN.
- Children should have their height and weight checked often while taking RITALIN. RITALIN treatment may be stopped if a problem is found during these check-ups.
- **In case of poisoning call your poison control center at 1-800-222-1222 right away, or go to the nearest hospital emergency room.**

What are the possible side effects of RITALIN?

RITALIN may cause serious side effects, including:

- See **“What is the most important information I should know about RITALIN?”** for information on reported heart and mental problems.
- **painful and prolonged erections (priapism)** have occurred with methylphenidate. If you or your child develops priapism, seek medical help right away. Because of the potential for lasting damage, priapism should be evaluated by a doctor immediately.
- **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 or your child have, numbness, pain, skin color change, or sensitivity to temperature in the 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 RITALIN.**
- **slowing of growth (height and weight) in children**

Common side effects include:

- | | | | | |
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| • fast heart beat | • abnormal heartbeat (palpitations) | • headache | • trouble sleeping | • nervousness |
| • sweating a lot | • decreased appetite | • dry mouth | • nausea | • stomach pain |

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 RITALIN?

- Store RITALIN in a safe place and in a tightly closed container at room temperature between 68°F to 77°F (20°C to 25°C).
- Protect from light.
- Dispose of remaining, unused, or expired RITALIN 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 RITALIN 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 (discard) RITALIN in the household trash.

- **Keep RITALIN and all medicines out of the reach of children.**

General information about the safe and effective use of RITALIN.

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

What are the ingredients in RITALIN?

Active ingredient: methylphenidate HCl

Inactive ingredients: D&C Yellow No.10 (5-mg and 20-mg tablets), FD&C Green No.3 (10-mg tablets), lactose, magnesium stearate, polyethylene glycol, starch (5-mg and 10-mg tablets), sucrose, talc, and tragacanth (20-mg tablets)

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