

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

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

RITALIN-SR is a federal controlled substance (CII) because it can be abused or lead to dependence. Keep RITALIN-SR in a safe place to prevent misuse and abuse. Selling or giving away RITALIN-SR may harm others, and is against the law. Tell your doctor if you or your child have ever 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-SR.

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

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-SR.

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

What is RITALIN-SR?

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

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

Who should not take RITALIN-SR?

RITALIN-SR should not be taken if you or your child:

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

RITALIN-SR may not be right for you or your child. Before starting RITALIN-SR, tell you 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-SR will harm your unborn baby.
 - There is a pregnancy registry for females who are exposed to ADHD medications, including RITALIN-SR, during pregnancy. The purpose of the registry is to collect information about the health of females exposed to RITALIN-SR and their baby. If you or your child becomes pregnant during treatment with RITALIN-SR, talk to your healthcare provider about registering with the National Pregnancy Registry of ADHD Medications at 1-866-961-2388 or visit online at <https://womensmentalhealth.org/adhd-medications/>.
- if you are breastfeeding or plan to breastfeed. RITALIN-SR passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with RITALIN-SR.

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-SR 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-SR.

Your doctor will decide whether RITALIN-SR 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.

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

How should RITALIN-SR be taken?

- Take RITALIN-SR exactly as prescribed. Your doctor may adjust the dose until it is right for you or your child.
- Take RITALIN-SR 30 to 45 minutes before a meal. The effect of a dose of RITALIN-SR usually lasts about 8 hours.
- **Do not chew or crush RITALIN-SR tablets.** Swallow RITALIN-SR tablets whole with water or other liquids. Tell your doctor if you or your child cannot swallow RITALIN-SR whole. A different medicine may need to be prescribed.
- From time-to-time, your doctor may stop RITALIN-SR treatment for a while to check ADHD symptoms.
- Your doctor may do regular checks of the blood, heart, and blood pressure while taking RITALIN-SR.
- Children should have their height and weight checked often while taking RITALIN-SR. RITALIN-SR 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-SR?

RITALIN-SR may cause serious side effects, including:

What are possible side effects of RITALIN-SR?

- see “**What is the most important information I should know about RITALIN-SR?**” 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-SR.**
- **Slowing of growth (height and weight) in children**

Common side effects include:

- | | | | | |
|-------------------|-------------------------------------|-------------|--------------------|----------------|
| • 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-SR?

- Store RITALIN-SR 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 moisture.
- 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-SR and all medicines out of the reach of children.**

General information about the safe and effective use of RITALIN-SR.

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-SR that is written for healthcare professionals. Do not use RITALIN-SR for a condition for which it was not prescribed. Do not give RITALIN-SR to other people, even if they have the same symptoms. It may harm them and it is against the law.

What are the ingredients in RITALIN-SR?

Active ingredient: methylphenidate HCl, USP

Inactive ingredients: Cetostearyl alcohol, lactose, magnesium stearate, mineral oil, povidone, titanium dioxide, and zein

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