

**MEDICATION GUIDE**  
**RITALIN LA<sup>®</sup> (rit-ah-lin LA)**  
**(methylphenidate hydrochloride)**  
**extended-release capsules CII**

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

**RITALIN LA is a federal controlled substance (CII) because it can be abused or lead to dependence. Keep RITALIN LA in a safe place to prevent misuse and abuse. Selling or giving away RITALIN LA 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 LA.

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

**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 LA.**

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

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**What is RITALIN LA?**

RITALIN LA is a central nervous system (CNS) stimulant prescription medicine. **It is used for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).** RITALIN LA may help increase attention and decrease impulsiveness and hyperactivity in patients with ADHD.

RITALIN LA should be used as a part of a total treatment program for ADHD that may include counseling or other therapies.

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

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**Who should not take RITALIN LA?**

**RITALIN LA should not be taken if you or your child:**

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

**RITALIN LA may not be right for you or your child. Before starting RITALIN LA, 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 LA will harm your unborn baby.
  - There is a pregnancy registry for females who are exposed to ADHD medications, including RITALIN LA during pregnancy. The purpose of the registry is to collect information about the health of females exposed to RITALIN LA and their baby. If you or your child becomes pregnant during treatment with RITALIN LA, 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 LA passes into your breast milk. Talk to your healthcare provider about the best way to feed the baby during treatment with RITALIN LA.

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

Your doctor will decide whether RITALIN LA 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 LA without talking to your doctor first.**

**How should RITALIN LA be taken?**

- Take RITALIN LA exactly as prescribed. Your doctor may adjust the dose until it is right for you or your child.
- Take RITALIN LA once a day in the morning. RITALIN LA is an extended-release capsule.
- **Do not chew or crush RITALIN LA capsules or the medicine inside the capsule.** Swallow RITALIN LA capsules whole with water or other liquids.
- If you cannot swallow the capsule whole, open it and sprinkle the medicine over a spoonful of applesauce. Swallow the applesauce and medicine mixture without chewing. Follow with a drink of water or other liquid.
- You should avoid drinking alcohol during treatment with RITALIN LA. This may cause a faster release of RITALIN LA.
- From time-to-time, your doctor may stop RITALIN LA treatment for a while to check ADHD symptoms.
- Your doctor may do regular checks of the blood, heart, and blood pressure while taking RITALIN LA. Children should have their height and weight checked often while taking RITALIN LA. RITALIN LA 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 possible side effects of RITALIN LA?**

- see “**What is the most important information I should know about RITALIN LA?**” 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 LA.**
- **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.**

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### **How should I store RITALIN LA?**

- Store RITALIN LA in a safe place and in a tightly closed container at room temperature, 68°F to 77°F (20°C to 25°C).
- Protect from moisture.
- Dispose of remaining, unused, or expired RITALIN LA 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 LA 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 LA in the household trash.
- **Keep RITALIN LA and all medicines out of the reach of children.**

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### **General information about the safe and effective use RITALIN LA.**

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

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### **What are the ingredients in RITALIN LA?**

**Active ingredient:** methylphenidate HCl

**Inactive ingredients:** ammonio methacrylate copolymer, black iron oxide (10 and 40 mg capsules only), gelatin, methacrylic acid copolymer, polyethylene glycol, red iron oxide (10 and 40 mg capsules only), sugar spheres, talc, titanium dioxide, triethyl citrate, and yellow iron oxide (10, 30, and 40 mg capsules).

RITALIN LA® is a trademark of Novartis AG.

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Novartis Pharmaceuticals Corporation  
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For more information, call 1-888-669-6682.

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