

## MEDICATION GUIDE

### RITALIN<sup>®</sup>

#### (methylphenidate hydrochloride tablets, USP) CII

Read the Medication Guide that comes with RITALIN<sup>®</sup> 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 RITALIN<sup>®</sup>.

#### **What is the most important information I should know about RITALIN<sup>®</sup>?**

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<sup>®</sup>.

Your doctor should check your or your child's blood pressure and heart rate regularly during treatment with RITALIN<sup>®</sup>.

**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<sup>®</sup>.**

##### **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 RITALIN<sup>®</sup>, especially seeing or hearing things that are not real, believing things that are not real, or are suspicious.**

#### **What Is RITALIN<sup>®</sup>?**

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

RITALIN<sup>®</sup> should be used as a part of a total treatment program for ADHD that may include counseling or other therapies.

RITALIN<sup>®</sup> is also used in the treatment of a sleep disorder called narcolepsy.

**RITALIN<sup>®</sup> is a federally controlled substance (CII) because it can be abused or lead to dependence. Keep**

**RITALIN<sup>®</sup> in a safe place to prevent misuse and abuse. Selling or giving away RITALIN<sup>®</sup> 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 RITALIN<sup>®</sup>?**

**RITALIN<sup>®</sup> 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 anti-depression medicine called a monoamine oxidase inhibitor or MAOI.
- are allergic to anything in RITALIN<sup>®</sup>. See the end of this Medication Guide for a complete list of ingredients.

RITALIN<sup>®</sup> should not be used in children less than 6 years old because it has not been studied in this age group.

**RITALIN<sup>®</sup> may not be right for you or your child. Before starting RITALIN<sup>®</sup> 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 breast-feeding.

### **Can RITALIN<sup>®</sup> 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.** RITALIN<sup>®</sup> 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<sup>®</sup>.

Your doctor will decide whether RITALIN<sup>®</sup> 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 RITALIN<sup>®</sup> without talking to your doctor first.**

### **How should RITALIN<sup>®</sup> be taken?**

- **Take RITALIN<sup>®</sup> 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<sup>®</sup> 30 to 45 minutes before a meal.
- From time to time, your doctor may stop RITALIN<sup>®</sup> treatment for a while to check ADHD symptoms.

- Your doctor may do regular checks of the blood, heart, and blood pressure while taking RITALIN<sup>®</sup>. Children should have their height and weight checked often while taking RITALIN<sup>®</sup>. RITALIN<sup>®</sup> treatment may be stopped if a problem is found during these check-ups.
- **If you or your child takes too much RITALIN<sup>®</sup> or overdoses, call your doctor or poison control center right away, or get emergency treatment.**

### **What are possible side effects of RITALIN<sup>®</sup>?**

See “**What is the most important information I should know about RITALIN<sup>®</sup>?**” 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:**

- headache
- stomach ache
- trouble sleeping
- nausea
- decreased appetite
- nervousness

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.

### **How should I store RITALIN<sup>®</sup>?**

- Store RITALIN in a safe place at room temperature, 59 to 86° F (15 to 30° C). Protect from light.
- **Keep RITALIN<sup>®</sup> and all medicines out of the reach of children.**

### **General information about RITALIN<sup>®</sup>**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use RITALIN<sup>®</sup> for a condition for which it was not prescribed. Do not give RITALIN<sup>®</sup> 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 RITALIN<sup>®</sup>. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about RITALIN<sup>®</sup> that was written for healthcare professionals. For more information about RITALIN<sup>®</sup> call 1-888-669-6682.

### **What are the ingredients in RITALIN<sup>®</sup>?**

**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).

**Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.**

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