MEDICATION GUIDE

RITALIN®

(methylphenidate hydrochloride, USP) tablets CII

Read the Medication Guide that comes with RITALIN 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.

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

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 your 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**

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

3. Circulation problems in fingers and toes [Peripheral vasculopathy, including Raynaud's phenomenon]: fingers or toes may feel numb, cool, painful, and/or may change color from pale, to blue, to red

- Tell your doctor if you have or your child has 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.**

What Is RITALIN?

RITALIN is a central nervous system 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.

RITALIN is a federally 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 (or have a family history of) ever abused or been dependent on alcohol, prescription medicines or street drugs.

Who should not take RITALIN?

RITALIN 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. See the end of this Medication Guide for a complete list of ingredients.

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

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
- tics or Tourette's syndrome
- seizures or have had an abnormal brain wave test (EEG)
- circulation problems in fingers or toes

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

Can RITALIN be taken with other medicines?

Tell your doctor about all of the medicines that you or your child takes including prescription and nonprescription 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
- 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 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.
- **If you or your child takes too much RITALIN or overdoses, call your doctor or poison control center right away, or get emergency treatment.**

What are possible side effects of RITALIN?

See **"What is the most important information I should know about RITALIN?"** 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
- painful and prolonged erections (priapism) have occurred with methylphenidate. If you or your child develop priapism, seek medical help right away. Because of the potential for lasting damage, priapism should be evaluated by a doctor immediately.

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?

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

General information about RITALIN.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. 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 condition. It may harm them and it is against the law.

This Medication Guide summarizes the most important information about RITALIN. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about RITALIN that was written for healthcare professionals. For more information about RITALIN call 1-888-669-6682.

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).

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.

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