

## General information about Ritalin®

## Ritalin® (methylphenidate hydrochloride)

(methylphenidate hydrochloride) tablets, 10 mg/15 mg

Read the Medication Guide that comes with Ritalin® (methylphenidate hydrochloride) tablets, and you or your child may learn something that will help you or your child use the medicine safely. There may be new information. This Medication Guide may not be all the information about Ritalin® (methylphenidate hydrochloride) tablets. Ask your doctor for more information about Ritalin® (methylphenidate hydrochloride) tablets.

What is the most important information I should know about Ritalin®?

The following have been reported with use of Ritalin® and other stimulant medications:

1. **Seizure-related problems.**
  - Seizures (convulsions) in patients who have heart problems or heart failure.
  - Seizures and heart effects in adults.
  - Seizures and heart problems in children.

Tell your doctor if you or your child have any heart problems, heart failure, high blood pressure, or if family history of these problems.

Some doctors should check you or your child carefully for heart problems before starting Ritalin®.

Some doctors should check you or your child's blood pressure and heart rate regularly during treatment with Ritalin®.

Tell your doctor right away if you or your child have any signs of heart problems such as chest pain, dizziness, fainting, or feeling like you are going to pass out.

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Ritalin® is also used for the treatment of a drug disorder called **attention deficit hyperactivity disorder (ADHD)**.

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## Column

## Ritalin® (methylphenidate hydrochloride)

## Important Warning about Ritalin

You can develop serious side effects including:

- heart-related problems
- mental (psychiatric) problems

## Uses

Ritalin® is a central nervous system stimulant that helps increase alertness and decrease impulsiveness and hyperactivity.

Ritalin® helps treat:

- Attention-Deficit/Hyperactivity Disorder (ADHD)
- a sleep disorder called narcolepsy

## How to take Ritalin

- Ritalin® is taken by mouth (po). Take Ritalin® as prescribed by your doctor.
- Take Ritalin® 30 to 60 minutes before eating. Ritalin® is usually taken 2 to 3 times a day.
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## Serious side effects

Stop taking this medicine and call your doctor right away if you have:

- a stroke or heart attack (infarct)
- increased blood pressure or heart rate
- new or worse irregular heartbeat
- new or worse aggressive behavior
- new psychotic or manic symptoms
- slowing of growth in children
- weight changes or blurred vision

## Common side effects

- Headache, stomach ache, trouble sleeping, dizziness, decreased appetite, nervousness, anxiety, and heart palpitations
- There can be common side effects of Ritalin®. Tell your doctor about any side effect that does not go away or gets worse.

## Ask your doctor before use

Tell your doctor if you:

- have heart problems, heart defects, or high blood pressure
- have mental problems including psychosis, anxiety, or depression
- have liver or kidney problems
- have seizures or have had an abnormal brain wave test (EEG)
- are pregnant, planning to become pregnant, or breastfeeding
- are taking anti-depression medicines including MAOIs, tricyclic antidepressants, blood pressure medicines, or used or always medicines that contain decongestants

## Specific Groups

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

## More Information

- Talk to your doctor or pharmacist about any questions you may have about this medicine.
- For more information about Ritalin® call Novartis Laboratories at 1-888-663-6683.
- You may report side effects to the FDA at 1-800-FDA-1088.

## Health Literacy

## SOME IMPORTANT THINGS TO KNOW ABOUT YOUR MEDICATION

|                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Brand Name:</b>           | Ritalin®                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Active Ingredient:</b>    | methylphenidate hydrochloride                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Purpose:</b>              | Ritalin® helps treat Attention-Deficit/Hyperactivity Disorder (ADHD) and a sleep disorder called narcolepsy.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Effects:</b>              | Ritalin® is a central nervous system stimulant that helps increase alertness and decrease impulsiveness and hyperactivity.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>How to take:</b>          | <ul style="list-style-type: none"> <li>• Ritalin® is taken by mouth (po). Take Ritalin® as prescribed by your doctor.</li> <li>• Take Ritalin® 30 to 60 minutes before eating. Ritalin® is usually taken 2 to 3 times a day.</li> <li>• Ritalin® is usually taken 2 to 3 times a day.</li> </ul>                                                                                                                                                                                                                                                                                                                 |
| <b>Warnings:</b>             | <ul style="list-style-type: none"> <li>• You can develop serious side effects including heart-related problems or mental (psychiatric) problems.</li> <li>• Ritalin® should not be used in children less than 6 years old because it has not been studied in this age group.</li> </ul>                                                                                                                                                                                                                                                                                                                          |
| <b>Ask before use:</b>       | <p><b>Tell your doctor before use if you:</b></p> <ul style="list-style-type: none"> <li>• have heart problems, heart defects, or high blood pressure</li> <li>• have mental problems including psychosis, anxiety, or depression</li> <li>• have liver or kidney problems</li> <li>• have seizures or have had an abnormal brain wave test (EEG)</li> <li>• are pregnant, planning to become pregnant, or breastfeeding</li> <li>• are taking anti-depression medicines including MAOIs, tricyclic antidepressants, blood pressure medicines, or used or always medicines that contain decongestants</li> </ul> |
| <b>Common side effects:</b>  | <p>There can be common side effects of Ritalin®. Tell your doctor about any side effect that does not go away or gets worse.</p> <ul style="list-style-type: none"> <li>• Headache</li> <li>• stomach ache</li> <li>• trouble sleeping</li> <li>• anxiety</li> <li>• decreased appetite</li> <li>• nervousness</li> <li>• dizziness</li> <li>• heart palpitations</li> </ul>                                                                                                                                                                                                                                     |
| <b>Serious side effects:</b> | <p><b>Stop taking this medicine and call your doctor right away if you:</b></p> <ul style="list-style-type: none"> <li>• have a stroke or heart attack (infarct)</li> <li>• have increased blood pressure or heart rate</li> <li>• have new or worse irregular heartbeat</li> <li>• have new or worse aggressive behavior</li> <li>• have new psychotic or manic symptoms</li> <li>• have slowing of growth in children</li> <li>• have weight changes or blurred vision</li> </ul>                                                                                                                              |
| <b>Questions:</b>            | <p>Talk to your doctor or pharmacist about any questions you may have about this medicine.</p> <p>For more information about Ritalin® call Novartis Laboratories at 1-888-663-6683.</p>                                                                                                                                                                                                                                                                                                                                                                                                                          |

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