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Health Topics

Drugs & Supplements

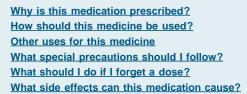
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**ESPAÑOL** 

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### Methylphenidate

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What should I know about storage and disposal of this medication?
In case of emergency/overdose
What other information should I know?
Brand names
Other names

#### **IMPORTANT WARNING:**

Methylphenidate can be habit-forming. Do not take a larger dose, take it more often, take it for a longer time, or take it in a different way than prescribed by your doctor. If you take too much methylphenidate, you may find that the medication no longer controls your symptoms, you may feel a need to take large amounts of the medication, and you may experience unusual changes in your behavior. Tell your doctor if you drink or have ever drunk large amounts of alcohol, use or have ever used street drugs, or have overused prescription medications.

Do not stop taking methylphenidate without talking to your doctor, especially if you have overused the medication. Your doctor will probably decrease your dose gradually and monitor you carefully during this time. You may develop severe depression if you suddenly stop taking methylphenidate after overusing it. Your doctor may need to monitor you carefully after you stop taking methylphenidate, even if you have not overused the medication, because your symptoms may worsen when treatment is stopped.

Do not sell, give away, or let anyone else take your medication. Selling or giving away methylphenidate may harm others and is against the law. Store methylphenidate in a safe place so no one else can take it accidentally or on purpose. Keep track of how much medication is left so you will know if any is missing.

Your doctor or pharmacist will give you the manufacturer's patient information sheet (Medication Guide) when you begin treatment with methylphenidate and each time you get more medication. Read the information carefully and ask your doctor or pharmacist if you have any questions. You can also visit the Food and Drug Administration (FDA) website (<a href="http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm">http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm</a>) or the manufacturer's website to obtain the Medication Guide.

### Why is this medication prescribed?

Methylphenidate is used as part of a treatment program to control symptoms of attention deficit hyperactivity disorder (ADHD; more difficulty focusing, controlling actions, and remaining still or quiet than other people who are the same age) in adults and children. Methylphenidate (Ritalin, Ritalin SR, Methylin, Methylin ER) is also used to treat narcolepsy (a sleep disorder that causes excessive daytime sleepiness and sudden attacks of sleep). Methylphenidate is in a class of medications called central nervous system (CNS) stimulants. It works by changing the amounts of certain natural substances in the brain.

#### How should this medicine be used?

Methylphenidate comes as an immediate-release tablet, a chewable tablet, a solution (liquid), an intermediate-acting (extended-release) tablet, a long-acting (extended-release) capsule, and a long-acting (extended-release) tablet. The long-acting tablet and capsules supply some medication right away and release the remaining amount as a steady dose of medication over a long time. All of these forms of methylphenidate are taken by mouth. The regular tablets (Ritalin, Methylin), chewable tablets (Methylin), and solution (Methylin) are usually taken two to three times a day by adults and twice a day

by children, preferably 35 to 40 minutes before meals. Adults who are taking three doses should take the last dose should be taken before 6:00 pm, so that the medication will not cause difficulty in falling asleep or staying asleep. The intermediate-acting extended release tablets (Ritalin SR, Metadate ER, Methylin ER) are usually taken once or twice a day, in the morning and sometimes in the early afternoon 30-45 minutes before a meal. The long-acting extended release capsule (Metadate CD) is usually taken once a day before breakfast; the long-acting extended-release tablet (Concerta) and capsule (Ritalin LA) are usually taken once a day in the morning with or without food.

Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take methylphenidate exactly as directed.

You should thoroughly chew the chewable tablets and then drink a full glass (at least 8 ounces [240 milliliters]) of water or other liquid. If you take the chewable tablet without enough liquid, the tablet may swell and block your throat and may cause you to choke. If you have chest pain, vomiting, or trouble swallowing or breathing after taking the chewable tablet, you should call your doctor or get emergency medical treatment immediately.

Swallow the intermediate acting and long-acting extended-release tablets and capsules whole; do not split, chew, or crush them. However, if you cannot swallow the long-acting capsules (Metadate CD, Ritalin LA), you may carefully open the capsules and sprinkle the entire contents on a tablespoon of cool or room temperature applesauce. Swallow (without chewing) this mixture immediately after preparation and then drink a glass of water to make sure you have swallowed all of the medicine. Do not store the mixture for future use.

Your doctor may start you on a low dose of methylphenidate and gradually increase your dose, not more often than once every week.

Your condition should improve during your treatment. Call your doctor if your symptoms worsen at any time during your treatment or do not improve after one month.

Your doctor may tell you to stop taking methylphenidate from time to time to see if the medication is still needed. Follow these directions carefully.

#### Other uses for this medicine Return to top

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

#### What special precautions should I follow? Return to top

Before taking methylphenidate,

- tell your doctor and pharmacist if you are allergic to methylphenidate or any other medications.
- tell your doctor if you are taking monoamine oxidase (MAO) inhibitors, including isocarboxazid (Marplan), phenelzine (Nardil), selegiline (Eldepryl, Emsam, Zelapar), and tranylcypromine (Parnate), or have stopped taking them during the past 14 days. Your doctor will probably tell you not to take methylphenidate until at least 14 days have passed since you last took an MAO inhibitor.
- tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention any of the following: anticoagulants ('blood thinners') such as warfarin (Coumadin); antidepressants such as clomipramine (Anafranil), desipramine (Norpramin), and imipramine (Tofranil); clonidine (Catapres); decongestants (cough and cold medications); guanabenz; guanfacine (Tenex); medications for high blood pressure; medications for seizures such as phenobarbital, phenytoin (Dilantin), and primidone (Mysoline); methyldopa (Aldomet); selective serotonin reuptake inhibitors (SSRIs) such as citalopram (Celexa), escitalopram (Lexapro), fluoxetine (Prozac, Sarafem, in Symbyax), fluvoxamine, paroxetine (Paxil), and sertraline (Zoloft); and venlafaxine (Effexor). If you are taking Ritalin LA, also tell your doctor if you take antacids or medications for heartburn or ulcers. Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- tell your doctor if you or anyone in your family has or has ever had Tourette's syndrome (a condition characterized by the need to perform repeated motions or to repeat sounds or words), facial or motor tics (repeated uncontrollable movements), or verbal tics (repetition of sounds or words that is hard to control). Also tell your doctor if you have glaucoma (increased pressure in the eye that may cause vision loss), an overactive thyroid gland, or feelings of anxiety, tension, or agitation. If you are taking the intermediate-acting extended-release tablet (Metadate ER) or the long-acting extended-release capsule (Metadate CD), tell your doctor if you have any condition that prevents you from digesting foods containing sugar, starch, or dairy products normally. Your doctor will probably tell you not to take methylphenidate if you have any of these conditions.tell your doctor if anyone in your family has or has ever had an irregular heartbeat or has died suddenly. Also tell your doctor if you have recently had a heart attack and if you have or have ever had a heart defect, high blood pressure, an irregular heartbeat, heart or blood vessel disease, hardening of the arteries, or other heart problems. Your doctor will examine you to see if your heart and blood vessels are healthy. Your doctor will probably tell you not to take methylphenidate if you have a heart condition or if there is a high risk that you may develop a heart condition.
- tell your doctor if you or anyone in your family has or has ever had depression, bipolar disorder (mood that changes to from depressed to abnormally excited), or mania (frenzied, abnormally excited mood) or has thought about or attempted suicide. Also tell your doctor if you have or ever have had seizures, an abnormal electroencephalogram (EEG; a test that measures electrical activity in the brain), or mental illness. If you are taking the chewable tablets, tell your doctor if you have trouble swallowing or if you have phenylketonuria (PKU, an inherited condition in which a special diet must be followed to prevent mental retardation). If you are taking the long-acting extended-release tablet (Concerta), tell your doctor if you have a narrowing or blockage of your digestive system.
- tell your doctor if you are pregnant, plan to become pregnant, or are breast-feeding. If you become pregnant while taking methylphenidate, call your doctor.
  - talk to your doctor about the risks and benefits of taking methylphenidate if you are 65 years of age or older. Older adults should not usually take

methylphenidate because it is not as safe as other medications that can be used to treat the same condition.

- if you are having surgery, including dental surgery, tell the doctor or dentist that you are taking methylphenidate.
- you should know that methylphenidate should be used as part of a total treatment program for ADHD, which may include counseling and special education. Make sure to follow all of your doctor's and/or therapist's instructions.

### What should I do if I forget a dose? Return to top

Take the missed dose as soon as you remember it. However, if it is almost time for your next scheduled dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

#### What side effects can this medication cause? Return to top

Methylphenidate may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- nervousness
- · difficulty falling asleep or staying asleep
- dizziness
- nausea
- vomiting
- · loss of appetite
- · stomach pain
- diarrhea
- heartburn
- · dry mouth
- headache
- muscle tightness
- · uncontrollable movement of a part of the body
- restlessness
- · numbness, burning, or tingling in the hands or feet
- decreased sexual desire
- · painful menstruation

Some side effects can be serious. If you experience any of the following symptoms, call your doctor immediately:

- fast, pounding, or irregular heartbeat
- · chest pain
- · shortness of breath
- · excessive tiredness
- · slow or difficult speech
- fainting
- · weakness or numbness of an arm or leg
- seizures
- changes in vision or blurred vision
- agitation
- believing things that are not true

- · feeling unusually suspicious of others
- · hallucinating (seeing things or hearing voices that do not exist)
- · motor tics or verbal tics
- depression
- · abnormally excited mood
- · mood changes
- fever
- hives
- rash
- · blistering or peeling skin
- itching
- · difficulty breathing or swallowing

Methylphenidate may cause sudden death in children and teenagers, especially children or teenagers with heart defects or serious heart problems. This medication also may cause sudden death, heart attack or stroke in adults, especially adults with heart defects or serious heart problems. Talk to your doctor about the risks of taking this medication.

Methylphenidate may slow children's growth or weight gain. Your child's doctor will watch his or her growth carefully. Talk to your child's doctor if you have concerns about your child's growth or weight gain while he or she is taking this medication. Talk to your child's doctor about the risks of giving methylphenidate to your child.

### What should I know about storage and disposal of this medication? Return to top

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature, away from light and excess heat and moisture (not in the bathroom). Store methylphenidate in a safe place so that no one else can take it accidentally or on purpose. Keep track of how many tablets or capsules are left so you will know if any are missing. Throw away any medication that is outdated or no longer needed. Talk to your pharmacist about the proper disposal of your medication.

### In case of emergency/overdose Return to top

In case of overdose, call your local poison control center at 1-800-222-1222. If the victim has collapsed or is not breathing, call local emergency services at 911.

Symptoms of overdose may include:

- vomiting
- agitation
- · uncontrollable shaking of a part of the body
- · muscle twitching
- seizures
- loss of consciousness
- · inappropriate happiness
- · confusion
- hallucinating (seeing things or hearing voices that do not exist)
- sweating
- flushing
- headache

- fever
- · fast, pounding, or irregular heartbeat
- · widening of pupils (black circles in the middle of the eyes)
- · dry mouth or nose

#### What other information should I know? Return to top

If you are taking methylphenidate long-acting tablets (Concerta), you may notice something that looks like a tablet in your stool. This is just the empty tablet shell, and this does not mean that you did not get your complete dose of medication.

Keep all appointments with your doctor and the laboratory. Your doctor may order certain lab tests to check your response to methylphenidate.

This prescription is not refillable. Be sure to schedule appointments with your doctor on a regular basis so that you do not run out of medication.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

#### Brand names Return to top

Concerta<sup>®</sup>

Methylin<sup>®</sup>

Metadate<sup>®</sup>

Ritalin<sup>®</sup>

#### Other names Return to top

· Methylphenidylacetate hydrochloride

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