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Methylphenidate

pronounced as (meth'' il fen' i date)

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 (<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm>)

[<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm>]) 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 (Methylin) 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), a long-acting (extended-release) suspension (liquid), an intermediate-acting (extended-release) tablet, a long-acting (extended-release) capsule, a long-acting (extended-release) tablet, a long-acting (extended-release) chewable tablet, and a long-acting (extended-release) orally disintegrating tablet (tablet that dissolves quickly in the mouth). The long-acting tablet, orally disintegrating tablets, and capsules supply some medication right away and release the remaining amount as a steady dose of medication over a longer time. All of these forms of methylphenidate are taken by mouth. The regular tablets, 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 before 6:00 pm, so that the medication will not cause difficulty in falling asleep or staying asleep. The intermediate-acting tablets are usually taken once or twice a day, in the morning and sometimes in the early afternoon 30 to 45 minutes before a meal. The long-acting capsule (Metadate CD) is usually taken once a day before breakfast; the long-acting tablet (Concerta), long-acting chewable tablet (Quillichew ER), long-acting suspension (Quillivant XR), and long-acting capsules (Aptensio XR, Ritalin LA) are usually taken once a day in the morning with or without food. The long-acting suspension (Quillivant XR) will begin to work sooner if it is taken with food. The long-acting orally disintegrating tablet (Cotempla XR-ODT) and the long-acting capsule (Adhansia XR) is usually taken once daily in the morning and should be taken consistently, either always with food or always without food. The long-acting capsule (Jornay PM) is usually taken once daily in the evening (between 6:30 pm and 9:30 pm), and should be taken consistently, at the same time every evening and either always with food or always 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.

Do not try to push the extended-release orally disintegrating tablet (Cotempla XR-ODT) through the blister pack foil. Instead, use dry hands to peel back the foil packaging. Immediately take out

the tablet and place it in your mouth. The tablet will quickly dissolve and can be swallowed with saliva; no water is needed to swallow the tablet.

You should thoroughly chew the immediate-release chewable tablets and then drink a full glass (at least 8 ounces [240 milliliters]) of water or other liquid. If you take the immediate-release 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 tablets and capsules whole; do not split, chew, or crush them. However, if you cannot swallow the long-acting capsules (Aptensio XR, Jornay PM, Metadate CD, Ritalin LA), you may carefully open the capsules and sprinkle the entire contents on a tablespoon of cool or room temperature applesauce, or for long-acting capsules (Adhansia XR), you may open the capsules and sprinkle the entire contents on a tablespoon of applesauce or yogurt. Swallow (without chewing) this mixture immediately after preparation (within 10 minutes if taking Adhansia XR) 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.

If you are taking the long-acting chewable tablet (Quillichew ER) and your doctor has told you to take part of the tablet to get the correct amount of your dose, break the 20 mg or 30 mg long-acting chewable tablet carefully along the lines that have been scored into it. However, the 40 mg long-acting chewable tablet is not scored and cannot be divided or split.

If you are taking the long-acting suspension (Quillivant XR), follow these steps to measure the dose:

1. Remove the bottle of medication and dosing dispenser from the box. Check to be sure that the bottle contains liquid medication. Call your pharmacist and do not use the medication if the bottle contains powder or if there is no dosing dispenser in the box.
2. Shake the bottle up and down for at least 10 seconds to mix the medication evenly.
3. Remove the bottle cap. Check that the bottle adapter has been inserted into top of the bottle.
4. If the bottle adapter has not been inserted into the top of the bottle, insert it by placing the bottom of the adapter into the opening of the bottle and pressing down firmly on it with your thumb. Call your pharmacist if the box does not contain a bottle adapter. Do not remove the bottle adapter from the bottle once it is inserted.
5. Insert the tip of the dosing dispenser into the bottle adapter and push the plunger all the way down.
6. Turn the bottle upside down.
7. Pull the plunger back to withdraw the amount of oral suspension prescribed by your doctor. If you are not sure how to correctly measure the dose your doctor has prescribed, ask your doctor or pharmacist.
8. Remove the dosing dispenser and slowly squirt the oral suspension directly into your mouth or your child's mouth.

9. Replace the cap on the bottle and close tightly.
10. Clean the dosing dispenser after each use by placing it in the dishwasher or by rinsing with tap water.

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 1 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.

Some methylphenidate products may not be able to be substituted for another. Ask your pharmacist if you have any questions about the type of methylphenidate product your doctor has prescribed.

Other uses for this medicine

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

What special precautions should I follow?

Before taking methylphenidate,

- tell your doctor and pharmacist if you are allergic to methylphenidate, to any other medications, aspirin (if taking Adhansia XR), tartrazine dye (a yellow dye in some processed foods and medications; if taking Adhansia XR), or any of the ingredients in the methylphenidate product you are taking. Ask your doctor or check the Medication Guide for a list of the ingredients.
- tell your doctor if you are taking monoamine oxidase (MAO) inhibitors, including isocarboxazid (Marplan), linezolid (Zyvox), methylene blue, phenelzine (Nardil), rasagiline (Azilect), 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, Jantoven); antidepressants such as clomipramine (Anafranil), desipramine (Norpramin), and imipramine (Tofranil); decongestants (cough and cold medications); medications for heartburn or ulcers such as esomeprazole (Nexium, in Vimovo), famotidine (Pepcid), omeprazole (Prilosec, in Zegerid), or pantoprazole (Protonix); medications for high blood pressure; medications for seizures such as phenobarbital, phenytoin (Dilantin, Phenytek), and primidone (Mysoline); methyl dopa; selective serotonin reuptake inhibitors (SSRIs) such as citalopram (Celexa), escitalopram (Lexapro), fluoxetine (Prozac, Sarafem, in Symbyax, others), fluvoxamine (Luvox), paroxetine (Brisdelle, Paxil, Pexeva), and sertraline (Zoloft); sodium bicarbonate (Arm and

Hammer Baking Soda, Soda Mint); 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. 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, cardiomyopathy (thickening of the heart muscle), or other heart problems. 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 from depressed to abnormally excited), 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), circulation problems in your fingers or toes, or mental illness. If you are taking the long-acting tablet (Concerta), tell your doctor if you have a narrowing or blockage of your digestive system.
- tell your doctor if you are pregnant or plan to become pregnant. If you become pregnant while taking methylphenidate, call your doctor.
- tell your doctor if you are breastfeeding or plan to breastfeed. If you are breastfeeding while taking methylphenidate your doctor may tell you to watch your baby closely for unusual agitation, difficulty sleeping, poor appetite, or weight loss.
- 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.
- be aware that you should not drink alcoholic beverages while taking the long-acting chewable tablet (Quillichew ER), the long-acting orally disintegrating tablet (Cotempla[®] XR-ODT), or the long-acting capsule (Adhansia XR or Jornay PM).
- if you have phenylketonuria (PKU, an inherited condition in which a special diet must be followed to prevent damage to your brain that can cause severe intellectual disability), you should know that the immediate-release and long-acting chewable tablets contain aspartame that forms phenylalanine.
- 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?

Take the missed dose as soon as you remember it. Talk to your doctor or pharmacist about how late in the day you should take a missed dose of your medication so that it will not cause difficulty in falling asleep or staying asleep. However, if it is almost time for your next scheduled dose, skip the missed dose and continue your regular dosing schedule. If you are taking the long-acting capsule (Jornay PM), take the missed dose as soon as you remember it that night. However, if it is already the next morning, skip the missed dose of the long-acting capsule (Jornay PM) 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?

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

- nervousness
- irritability
- difficulty falling asleep or staying asleep
- dizziness
- nausea
- vomiting
- loss of appetite
- weight loss
- stomach pain
- diarrhea
- heartburn
- dry mouth
- headache
- muscle tightness
- drowsiness
- uncontrollable movement of a part of the body
- restlessness
- decreased sexual desire
- heavy sweating
- back pain

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

- 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
- frequent, painful erections
- erection that lasts longer than 4 hours
- numbness, pain, or sensitivity to temperature in the fingers or toes
- skin color change from pale to blue to red in the fingers or toes
- unexplained wounds on the fingers or toes
- fever
- hives
- rash
- blistering or peeling skin
- itching
- swelling of the eyes, face, lips, mouth, tongue, or throat
- hoarseness

- difficulty breathing or swallowing

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?

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 or how much liquid is left so you will know if any medication is missing.

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>]) for more information if you do not have access to a take-back program.

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>] . If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

Symptoms of overdose may include the following:

- vomiting
- nausea
- diarrhea
- fainting, blurred vision, or dizziness
- restlessness

- abnormally rapid breathing
- anxiety
- 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
- muscle weakness, fatigue, or dark urine

What other information should I know?

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 check your blood pressure and heart rate and 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

- Adhansia XR[®]
- Aptensio XR[®]
- Concerta[®]
- Cotempla[®] XR-ODT
- Jornay PM[®]

- Metadate[®] CD
- Metadate[®] ER[¶]
- Methylin[®]
- Methylin[®] ER[¶]
- Quillichew[®] ER

- Quillivant[®] XR
- Ritalin[®][¶]
- Ritalin[®] LA
- Ritalin[®] SR[¶]

Other names

- Methylphenidylacetate hydrochloride

[¶] - This branded product is no longer on the market. Generic alternatives may be available.

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