

- Ritalin®, Methylin® (methylphenidate, immediate release)
 - o Tablets: 5 mg, 10 mg, 20 mg
 - o Chewable tablets: 2.5 mg, 5 mg,
 - o Liquid: 5 mg/5 mL, 10 mg/5 mL
- Ritalin LA® (methylphenidate, extended release)
 - o Capsules: 10 mg, 20 mg, 30 mg, 40 mg.
- Aptensio XR® (methylphenidate, extended release)
 - Capsules: 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 50 mg, 60 mg
- Concerta® (methylphenidate, extended release)
 - Caplets: 18 mg, 27 mg, 36 mg, 54
- Relexxii ® (methylphenidate, extended release)
 - Tablets: 72mg
- Cotempla XR-ODT® (methylphenidate, extended release orally disintegrating)
 - o Tablets: 8.6mg, 17.3mg, 25.9mg
- Daytrana® (methylphenidate patch)
 - o Patch: 10 mg, 15 mg, 20 mg, 30
- QuilliChew ER® (methylphenidate extended release chewable)
 - o Tablet: 20 mg, 30 mg, 40mg
- Quillivant XR® (methylphenidate, extended-release oral suspension)
 - o Liquid: 25 mg/5 mL
 - o Capsules: 5 mg, 10 mg, 15 mg, 20 mg, 25 mg, 30 mg, 35 mg
- Jornay PM® (methylphenidate HCL, extended release)
 - o Capsules: 20 mg, 40 mg, 60 mg, 80 mg, 100 mg
- Azstarys ® (serdexmethylphenidate and dexmethylphenidate)
 - Capsules: 26.1/5.2mg, 39.2/7.8mg, 52.3/10.4mg
- Methylphenidate extended release
 - o CD Capsules: 10 mg, 20mg, 30 mg, 40 mg, 50 mg, 60 mg
 - o Caplets: 18 mg, 27 mg, 36 mg, 54
 - ER Tablets: 10 mg, 20 mg

All FDA warnings are at the end of this fact sheet. Please consult them before taking this medication.

If you or someone you know is in crisis, call/text 988 to speak with a trained crisis counselor 24/7 and/or call 911 for emergency services. A help line and other resources are also available through the National Alliance on Mental Illness at <u>nami.orq</u>.



What is methylphenidate or dexmethylphenidate and what does it treat?

Methylphenidate, dexmethylphenidate, and serdexmethylphenidate prescription medications that are used to treat children, adolescents, and adults with attention-deficit hyperactivity disorder (ADHD). They are in the class of medications known as stimulants.

Symptoms of ADHD interfere with an individual's ability to function at school or work or in social settings and include:

- Inattention (e.g., making careless mistakes, losing things necessary for tasks)
- Hyperactivity (e.g., inability to sit still)
- Impulsivity (e.g., interrupting or intruding on others)

Hyperactivity is less common in adults. A person may have severe inattention without hyperactivity or impulsivity.

Methylphenidate, dexmethylphenidate, or serdexmethylphenidate are used in addition to non-medication treatments to manage ADHD symptoms.

What is the most important information I should know about methylphenidate or dexmethylphenidate?

Although some symptoms may improve within days of starting methylphenidate or dexmethylphenidate, it may take several weeks before you notice the full benefits of the medication.

Are there specific concerns about methylphenidate or dexmethylphenidate and pregnancy?

If you are planning on becoming pregnant, notify your health care provider so that he/she can best manage your medications. There is limited information on the effects of methylphenidate, dexmethylphenidate and serdexmethylphenidate in human pregnancy. Therefore, it is important to discuss your risk vs benefit decision with your doctor and caregivers.

Caution is also advised while breastfeeding since there is limited information available about the safety of methylphenidate, dexmethylphenidate and serdexmethylphenidate for the baby while breastfeeding. It is possible that certain doses may interfere with milk production. Infants exposed to methylphenidate, dexmethylphenidate, or serdexmethylphenidate through the breast milk may need to be monitored for agitation, poor feeding and reduced weight gain.



What should I discuss with my health care provider before taking methylphenidate or dexmethylphenidate?

- The most bothersome symptoms of your condition
- If you have thoughts of suicide
- Medications you have taken in the past for your condition, whether they were effective or caused any adverse effects
- If you experience side effects from your medications as some side effects may pass with time, but others may require an adjustment in the medication.
- Any other psychiatric or medical problems you have
- All other medications you are currently taking and any medication allergies you have. This will help your prescriber assess for potential drug interactions.
- Other non-medication treatment you are receiving (such as psychotherapy (i.e., talk therapy) or substance abuse treatment). Your provider can explain how these different treatments work with the medication.
- If you are pregnant, plan to become pregnant, or are breastfeeding
- If you drink alcohol or use drugs

How should I take methylphenidate or dexmethylphenidate?

Methylphenidate or dexmethylphenidate is usually taken one to three times per day with or without food.

- Immediate release formulations may need to be given two to three times a day to provide symptom coverage throughout
- Extended release formulations may be given once a day as they last for 8 to 12 hours after they are taken.
- Certain forms of methylphenidate or dexmethylphenidate may have special instructions:
 - Concerta® Tablet: should always be swallowed whole (no cutting, chewing or crushing) with water or other liquid. The tablet shell may be seen in the stool because of the way it is absorbed in the stomach. It should not be given to those who have a history of stomach bypass surgery or narrowing of the intestines.
 - Cotempla XR-ODT® should always be removed from the package by peeling back the foil on the blister pack. Never push the tablet through the foil. Once the blister is open, put the tablet immediately on the tongue with dry hands. Let it dissolve without chewing or crushing.
 - Daytrana® (Methylphenidate) Patch: should be applied to a clean, hair-free area in the morning and removed approximately 9 hours later for an approximate 12 hour duration of action.
 - Jornay PM® Capsule: should be given in the evening as it takes 10 hours for its effects to start. Jornay PM® and other methylphenidate capsules can be opened and sprinkled onto applesauce if someone has trouble swallowing. If the capsule is opened, never chew the beads as this can make the medicine not work as well or cause more side effects.
 - Quillivant XR® (Methylphenidate Extended Release) Oral Suspension should be shaken for 10 seconds prior to drawing up the dose. Be sure to use the oral syringe that is provided to measure each dose. The oral syringe should then be cleaned after each use.

While the dose usually varies, your health care provider will determine the dose that is right for you based upon your response.

What happens if I miss a dose of methylphenidate or dexmethylphenidate?

If you miss a dose of methylphenidate or dexmethylphenidate, take it as soon as you remember it, if it is not too close to when your next dose is due—discuss this with your health care provider. Do not double your next dose or take more than what is prescribed. Do not take a missed dose after 5:00 PM, as this may interfere with sleep.

What should I avoid while taking methylphenidate or dexmethylphenidate?

Avoid drinking alcohol or using illegal drugs while you are taking methylphenidate or dexmethylphenidate as the beneficial effects of the medication may be decreased and adverse effects may be increased.

What happens if I overdose with methylphenidate or dexmethylphenidate?

If an overdose occurs, whether intentional or accidental, immediate medical attention may be necessary. Call your doctor or emergency medical service (911). You may also contact the poison control center (1-800-222-1222).



Overdosing with methylphenidate or dexmethylphenidate may lead to nausea and vomiting, rapid heartbeat, abnormal heart rhythms, paranoia, hallucinations, and seizures.

What are the possible side effects of methylphenidate or dexmethylphenidate?

Common side effects

Upset stomach, loss of appetite, insomnia, and mild anxiety

Rare side effects

Contact your health care provider if any of the following occur while taking methylphenidate or dexmethylphenidate:

- Significant increases in blood pressure or heart rate, shortness of breath, fatigue
- Severe anxiety, panic attacks, mania, hallucinations, paranoia or delusions
- Severe muscle pain, weakness, signs of dehydration, or dark urine
- Prolonged or painful erection
- Changes of feeling or color in your fingers or toes

Serious side effects

Medications like methylphenidate or dexmethylphenidate should be avoided in individuals who have a heart defect (structural abnormalities), uncontrolled high blood pressure, or a disorder of the heart or blood vessels.

Both methylphenidate and dexmethylphenidate are rarely associated with clinically significant increases in blood pressure or heart rate. Blood pressure and heart rate should be monitored before starting medication, and then weekly while adjusting the dose and then every 1 to 3 months or when side effects like "racing heart", shortness of breath or exercise fatigue becomes problematic.

Are there any risks for taking methylphenidate or dexmethylphenidate for long periods of time?

Both methylphenidate and dexmethylphenidate are Schedule II controlled substances. There is a risk of physical and/or emotional dependence when it is taken for long periods of time.

Although treatment with these medications can slow growth, many studies have shown that these changes are small, and children may catch-up with growth over time, therefore should not be a concern for most children. Height, weight, and eating habits should be discussed before treatment starts and regularly during treatment. If you are concerned about a child's growth, discuss other possible treatments with your child's health care providers.

What other medications may interact with methylphenidate or dexmethylphenidate?

Medications used to treat depression such as tricyclic antidepressants (TCA) and monoamine oxidase inhibitors (MAOIs) can interact with methylphenidate and dexmethylphenidate resulting in serious reactions, including high body temperature, high blood pressure, and seizures. Tell your health care provider if you are starting or have recently stopped taking any of these medications.

Methylphenidate and dexmethylphenidate should not be taken with or within 2 weeks of MAOIs. These include phenelzine (Nardil®), tranylcypromine (Parnate®), and selegiline (Emsam). Taking methylphenidate or dexmethylphenidate with or within 2 weeks of MAOIs can result in seizures, fever or dangerously high blood pressure that can lead to death.

The following medications may increase the levels and/or effects of methylphenidate or dexmethylphenidate:

• Atomoxetine (Strattera®), caffeine, alcohol, phenylephrine, fluoxetine (Prozac®), bupropion (Wellbutrin®), venlafaxine (Effexor®), duloxetine (Cymbalta®), modafinil (Provigil®), and armodafinil (Nuvigil®)

Methylphenidate or dexmethylphenidate may **increase** the levels and effects of some seizure medications such as phenobarbital or phenytoin, coumadin, and tricyclic antidepressants such as desipramine or clomipramine.

Methylphenidate or dexmethylphenidate may **decrease** the levels and effects of some blood pressure medications such as clonidine, guanfacine, guanethidine and guanadrel.



How long does it take for methylphenidate or dexmethylphenidate to work?

Although you may experience beneficial effects from methylphenidate or dexmethylphenidate within a few days of starting the medication, it often takes several weeks to get the full effect of the medication. Your health care provider may also need to adjust gradually the dose to find the dose that works best for you.

Summary of Black Box Warnings

Abuse/Dependence

Long-term use of methylphenidate or dexmethylphenidate may lead to dependence. Physical dependence is when someone experiences withdrawal symptoms (ex: changes in mood, sleep, appetite, agitation) when a medication is suddenly stopped or decreased. Amphetamines also have a high potential for abuse. Abuse is when someone has craving for a drug, limited control over drug use, compulsive use or continued use of that drug despite harm. Particular attention should be paid to the possibility of obtaining methylphenidate or dexmethylphenidate products for non-therapeutic use or distribution to others. People being prescribed methylphenidate or dexmethylphenidate products should store them in a safe (preferably locked) place to prevent abuse.

Important Disclosure: This information is being provided as a community outreach effort of the American Association of Psychiatric Pharmacists. This information is for educational and informational purposes only and is not medical advice. This information contains a summary of important points and is not an exhaustive review of information about the medication. Always seek the advice of a physician or other qualified medical professional with any questions you may have regarding medications or medical conditions. Never delay seeking professional medical advice or disregard medical professional advice as a result of any information provided herein. The American Association of Psychiatric Pharmacists disclaims any and all liability alleged as a result of the information provided herein.