

MEDICATION GUIDE

Dexmethylphenidate Hydrochloride Extended-Release Capsules (dex" meth il fen' i date hye" droe klor' ide) for oral use, CII

What is the most important information I should know about dexmethylphenidate hydrochloride extended-release capsules?

Dexmethylphenidate hydrochloride extended-release capsules may cause serious side effects, including:

- **Abuse, misuse, and addiction.** Dexmethylphenidate hydrochloride extended-release capsules has a high chance for abuse and misuse and may lead to substance use problems, including addiction. Misuse and abuse of dexmethylphenidate hydrochloride extended-release capsules, other methylphenidate containing medicines, and amphetamine containing medicines, can lead to overdose and death. The risk of overdose and death is increased with higher doses of dexmethylphenidate hydrochloride extended-release capsules or when it is used in ways that are not approved, such as snorting or injection.
 - Your healthcare provider should check you or your child's risk for abuse, misuse, and addiction before starting treatment with dexmethylphenidate hydrochloride extended-release capsules and will monitor you or your child during treatment.
 - Dexmethylphenidate hydrochloride extended-release capsules may lead to physical dependence after prolonged use, even if taken as directed by your healthcare provider.
 - Do not give dexmethylphenidate hydrochloride extended-release capsules to anyone else. See **"What is dexmethylphenidate hydrochloride extended-release capsules?"** for more information.
 - Keep dexmethylphenidate hydrochloride extended-release capsules in a safe place and properly dispose of any unused medicine. See **"How should I store dexmethylphenidate hydrochloride extended-release capsules?"** for more information.
 - Tell your healthcare provider if you or your child have ever abused or been dependent on alcohol, prescription medicines, or street drugs.
- **Risks for people with serious heart disease.** Sudden death has happened in people who have heart defects or other serious heart disease.

Your healthcare provider should check you or your child carefully for heart problems before starting dexmethylphenidate hydrochloride extended-release capsules. Tell your healthcare provider if you or your child have any heart problems, heart disease, or heart defects.

Call your healthcare provider or go to the nearest hospital emergency room right away if you or your child has any signs of heart problems, such as chest pain, shortness of breath, or fainting while taking dexmethylphenidate hydrochloride extended-release capsules.

- **Increased blood pressure and heart rate.** Your healthcare provider should check you or your child's blood pressure and heart rate regularly during treatment with dexmethylphenidate hydrochloride extended-release capsules.
- **Mental (psychiatric) problems:**
All Patients
 - new or worse behavior and thought problems
 - new or worse bipolar illness
 - new psychotic symptoms (such as hearing voices, believing things that are not true, are suspicious) or new manic symptoms

Tell your healthcare provider about any mental problems you or your child have, or about a family history of suicide, bipolar illness, or depression.

Call your healthcare provider right away if you or your child have any new or worsening mental symptoms or problems while taking dexamethylphenidate hydrochloride extended-release capsules, especially seeing or hearing things that are not real, believing things that are not real, or are suspicious.

What are dexamethylphenidate hydrochloride extended-release capsules?

- Dexamethylphenidate hydrochloride extended-release capsule is a central nervous system stimulant (CNS) prescription medicine. It is used for the treatment of Attention-Deficit Hyperactivity Disorder (ADHD). Dexamethylphenidate hydrochloride extended-release capsules may help increase attention and decrease impulsiveness and hyperactivity in patients with ADHD.
- Dexamethylphenidate hydrochloride extended-release capsules should be used as a part of a total treatment program for ADHD that may include counseling or other therapies.

Dexamethylphenidate hydrochloride extended-release capsules are not recommended for use in children under 6 years of age with ADHD.

Dexamethylphenidate hydrochloride extended-release capsule is a federally controlled substance (CII) because it contains dexamethylphenidate that can be a target for people who abuse prescription medicines or street drugs. Keep dexamethylphenidate hydrochloride extended-release capsules in a safe place to protect it from theft. Never give your dexamethylphenidate hydrochloride extended-release capsules to anyone else because it may cause death or harm them. Selling or giving away dexamethylphenidate hydrochloride extended-release capsules may harm others and is against the law.

Who should not take dexamethylphenidate hydrochloride extended-release capsules?

Dexamethylphenidate hydrochloride extended-release capsules should not be taken if you or your child:

- are allergic to methylphenidate hydrochloride, or any of the ingredients in dexamethylphenidate hydrochloride extended-release capsules. See the end of this Medication Guide for a complete list of ingredients in dexamethylphenidate hydrochloride extended-release capsules.
- are taking or have taken within the past 14 days an anti-depression medicine called a monoamine oxidase inhibitor (MAOI).

Dexamethylphenidate hydrochloride extended-release capsules may not be right for you or your child. Before starting dexamethylphenidate hydrochloride extended-release capsules, tell your or your child's healthcare provider about all health conditions (or a family history of), including:

- heart problems, heart, disease, heart defects, or high blood pressure
- mental problems, including psychosis, mania, bipolar illness, or depression
- circulation problems in fingers or toes
- have eye problems, including increased pressure in your eye, glaucoma, or problems with your close-up vision (farsightedness)
- have or had repeated movements or sounds (tics) or Tourette's syndrome, or have a family history of tics or Tourette's syndrome.
- if you are pregnant or plan to become pregnant. It is not known if dexamethylphenidate hydrochloride will harm your unborn baby.
 - o There is a pregnancy registry for females who are exposed to ADHD medications, including dexamethylphenidate hydrochloride extended-release capsules, during pregnancy. The purpose of the registry is to collect information about the health of females exposed to dexamethylphenidate hydrochloride extended-release capsules and their baby. If you or your child becomes pregnant during treatment with dexamethylphenidate hydrochloride extended-release capsules, talk to your healthcare provider about registering with the National Pregnancy Registry of ADHD medications at 1-866-961-2388 or visit online at <https://womensmentalhealth.org/adhd-medications/>.
- if you are breastfeeding or plan to breastfeed. Dexamethylphenidate hydrochloride passes into your breast milk. Talk to your healthcare provider about the best way to feed the baby during treatment with dexamethylphenidate hydrochloride extended-release capsules.

Tell your healthcare provider about all of the medicines that you or your child takes, including prescription and

over-the-counter medicines, vitamins, and herbal supplements. Dexmethylphenidate hydrochloride extended-release capsules 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 dexmethylphenidate hydrochloride extended-release capsules.

Your healthcare provider will decide whether dexmethylphenidate hydrochloride extended-release capsules can be taken with other medicines.

Especially tell your healthcare provider if you or your child takes:

- anti-depression medicines, including MAOIs
- blood pressure medicines (anti-hypertensive)

Know the medicines that you or your child takes. Keep a list of your medicines with you to show your healthcare provider and pharmacist.

- You should not take dexmethylphenidate hydrochloride extended-release capsules on the day of your operation if a certain type of anesthetic is used. This is because there is a chance of a sudden rise in blood pressure and heart rate during the operation.

Do not start any new medicine while taking dexmethylphenidate hydrochloride extended-release capsules without talking to your healthcare provider first.

How should dexmethylphenidate hydrochloride extended-release capsules be taken?

- Take dexmethylphenidate hydrochloride extended-release capsules exactly as prescribed. Your healthcare provider may adjust the dose until it is right for you or your child.
- Take dexmethylphenidate hydrochloride extended-release capsule once each day in the morning. Dexmethylphenidate hydrochloride extended-release capsules is an extended-release capsule.
- Dexmethylphenidate hydrochloride extended-release capsules can be taken with or without food. Taking dexmethylphenidate hydrochloride extended-release capsules with food may slow the time it takes for the medicine to start working.
- Swallow dexmethylphenidate hydrochloride extended-release capsules whole with water or other liquids. Do not chew, crush, or divide the capsules or the beads in the capsule. If you or your child cannot swallow the capsule, open it and sprinkle the small beads of medicine over a spoonful of applesauce and swallow it right away without chewing.
- Your healthcare provider may do regular checks of the blood, heart, and blood pressure while taking dexmethylphenidate hydrochloride extended-release capsules.
- Children should have their height and weight checked often while taking dexmethylphenidate hydrochloride extended-release capsules. Dexmethylphenidate hydrochloride extended-release capsules treatment may be stopped if a problem is found during these check-ups.

If you or your child take too much dexmethylphenidate hydrochloride extended-release capsules, call your healthcare provider or Poison Help line at 1-800-222-1222 or go to the nearest hospital emergency room right away.

What are the possible side effects of dexmethylphenidate hydrochloride extended-release capsules?

Dexmethylphenidate hydrochloride extended-release capsules may cause serious side effects, including:

- see “**What is the most important information I should know about dexmethylphenidate hydrochloride extended-release capsules?**” for information on reported heart and mental problems.
- **painful and prolonged erections (priapism)** have occurred with methylphenidate. If you or your child develops priapism, seek medical help right away. Because of the potential for lasting damage, priapism should be evaluated by a healthcare provider immediately.
- **circulation problems in fingers and toes** (peripheral vasculopathy, including Raynaud’s phenomenon):
 - fingers or toes may feel numb, cool, painful
 - fingers or toes may change color from pale, to blue, to red

Tell your healthcare provider if you or your child have, numbness, pain, skin color change, or sensitivity to temperature in the fingers or toes.

- **Call your healthcare provider right away if you have or your child has any signs of unexplained wounds appearing on fingers or toes while taking dexmethylphenidate hydrochloride extended-release capsules.**

- **Slowing of growth (height and weight) in children.** Children should have their height and weight checked often during treatment with dexamethylphenidate hydrochloride extended-release capsules. Dexamethylphenidate hydrochloride extended-release capsules treatment may be stopped if your child is not growing or gaining weight.
- **Eye problems (increased pressure in the eye and glaucoma).** Call your healthcare provider right away if you or your child develop changes in your vision or eye pain, swelling, or redness.
- **New or worsening tics or worsening Tourette's syndrome.** Tell your healthcare provider if you or your child get any new or worsening tics or worsening Tourette's syndrome during treatment with dexamethylphenidate hydrochloride extended-release capsules.

Common side effects include:

Children (6 to 17 years)

- dyspepsia
- decreased appetite
- headache
- anxiety

Adults

- dry mouth
- dyspepsia
- headache
- anxiety
- pharyngolaryngeal pain

Call your doctor for medical advice about side effects. **You may report side effects to FDA at 1-800-FDA-1088.**

How should I store dexamethylphenidate hydrochloride extended-release capsules?

- Store dexamethylphenidate hydrochloride extended-release capsules in a safe place and in a tightly closed container at room temperature between 68°F to 77°F (20°C to 25°C).
- Dispose of remaining, unused, or expired dexamethylphenidate hydrochloride extended-release capsules by a medicine take-back program at a U.S. Drug Enforcement Administration (DEA) authorized collection site. If no take-back program or DEA authorized collector is available, mix dexamethylphenidate hydrochloride extended-release capsules with an undesirable, nontoxic substance such as dirt, cat litter, or used coffee grounds to make it less appealing to children and pets. Place the mixture in a container, such as a sealed plastic bag and throw away dexamethylphenidate hydrochloride extended-release capsules in the household trash. Visit www.fda.gov/drugdisposal for additional information on disposal of unused medicine.
- **Keep dexamethylphenidate hydrochloride extended-release capsules and all medicines out of the reach of children.**

General information about the safe and effective use of dexamethylphenidate hydrochloride extended-release capsules.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. You can ask your pharmacist or healthcare provider for information about dexamethylphenidate hydrochloride extended-release capsules that is written for healthcare professionals. Do not use dexamethylphenidate hydrochloride extended-release capsules for a condition for which it was not prescribed. Do not give dexamethylphenidate hydrochloride extended-release capsules to other people, even if they have the same symptoms that you have. It may harm them and it is against the law.

What are the ingredients in dexamethylphenidate hydrochloride extended-release capsules?

Active ingredient: dexamethylphenidate hydrochloride

Inactive ingredients: ammonio methacrylate copolymer, gelatin, methacrylic acid and methyl methacrylate copolymer, polyethylene glycol, sugar spheres (which contain sucrose and starch), talc, titanium dioxide, and triethyl citrate. The 5 mg, 25 mg and 35 mg capsule also contains D&C red #28. The 15 mg and 40 mg capsule also contains D&C yellow #10. The 5 mg, 15 mg, 25 mg, 35 mg, and 40 mg capsule also contains FD&C blue #1. The 10 mg, 30 mg and 35 mg capsule also contains FD&C yellow #6. In addition, capsule imprinting ink contains ammonium hydroxide, black iron oxide, propylene glycol and shellac glaze.

Manufactured By:

Granules Pharmaceuticals Inc.,
Chantilly, VA 20151

For more information, call 1-877-770-3183.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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