

MEDICATION GUIDE

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

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

Dexmethylphenidate hydrochloride extended-release capsules are a federal controlled substance (CII) because it can be abused or lead to dependence. Keep dexmethylphenidate hydrochloride extended-release capsules in a safe place to prevent misuse and abuse. Selling or giving away dexmethylphenidate hydrochloride extended-release capsules may harm others, and is against the law.

Tell your doctor if you or your child have abused or been dependent on alcohol, prescription medicines or street drugs.

The following have been reported with use of methylphenidate hydrochloride and other stimulant medicines.

1. Heart-related problems:

- **sudden death in patients who have heart problems or heart defects**
- **stroke and heart attack in adults**
- **increased blood pressure and heart rate**

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

Your doctor should check you or your child carefully for heart problems before starting dexmethylphenidate hydrochloride extended-release capsules.

Your doctor should check you or your child's blood pressure and heart rate regularly during treatment with dexmethylphenidate hydrochloride extended-release capsules.

Call your doctor 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.

2. Mental (psychiatric) problems:

All Patients

- **new or worse behavior and thought problems**
- **new or worse bipolar illness**
- **new or worse aggressive behavior or hostility**
- **new psychotic symptoms (such as hearing voices, believing things that are not true, are suspicious) or new manic symptoms**

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

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

What are dexmethylphenidate hydrochloride extended-release capsules?

- Dexmethylphenidate hydrochloride extended-release capsule is a central nervous system stimulant (CNS) prescription medicine. **It is used for the treatment of Attention Deficit and Hyperactivity Disorder (ADHD).** Dexmethylphenidate hydrochloride extended-release capsules may help increase attention and decrease impulsiveness and hyperactivity in patients with ADHD.

- Dexmethylphenidate hydrochloride extended-release capsules should be used as a part of a total treatment program for ADHD that may include counseling or other therapies.

Who should not take dexmethylphenidate hydrochloride extended-release capsules:

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

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

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

- heart problems, heart defects, high blood pressure
- mental problems, including psychosis, mania, bipolar illness, or depression
- circulation problems in fingers or toes
- if you are pregnant or plan to become pregnant. It is not known if dexmethylphenidate hydrochloride will harm your unborn baby.
 - There is a pregnancy registry for females who are exposed to ADHD medications, including Dexmethylphenidate hydrochloride extended-release capsules, during pregnancy. The purpose of the registry is to collect information about the health of females exposed to dexmethylphenidate hydrochloride extended-release capsules and their baby. If you or your child becomes pregnant during treatment with dexmethylphenidate hydrochloride extended-release capsules, talk to your healthcare provider about registering with the National Pregnancy Registry of ADHD medications at 1-866961-2388 or visit online at <https://womensmentalhealth.org/adhd-medications/>.
- if you are breastfeeding or plan to breastfeed. Dexmethylphenidate hydrochloride passes into your breast milk. Talk to your healthcare provider about the best way to feed the baby during treatment with dexmethylphenidate hydrochloride extended-release capsules. **Tell your doctor 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 doctor will decide whether dexmethylphenidate hydrochloride extended-release capsules can be taken with other medicines.

Especially tell your doctor 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 doctor and pharmacist.

- You should not take Dexmethylphenidate hydrochloride extended-release capsule 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 doctor first.

How should dexamethylphenidate hydrochloride extended-release capsules be taken?

- Take dexamethylphenidate hydrochloride extended-release capsules exactly as prescribed. Your doctor may adjust the dose until it is right for you or your child.
- Take dexamethylphenidate hydrochloride extended-release capsule once each day in the morning. Dexamethylphenidate hydrochloride extended-release capsules is an extended-release capsule.
- Dexamethylphenidate hydrochloride extended-release capsules can be taken with or without food. Taking dexamethylphenidate hydrochloride extended-release capsules with food may slow the time it takes for the medicine to start working.
- Swallow dexamethylphenidate 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.
- From time to time, your doctor may stop dexamethylphenidate hydrochloride extended-release capsules treatment for a while to check ADHD symptoms.
- Your doctor may do regular checks of the blood, heart, and blood pressure while taking dexamethylphenidate hydrochloride extended-release capsules.
- Children should have their height and weight checked often while taking dexamethylphenidate hydrochloride extended-release capsules. Dexamethylphenidate hydrochloride extended-release capsules treatment may be stopped if a problem is found during these check-ups.
- **In case of poisoning, call your poison control center at 1-800-222-1222 right away, or go to the nearest hospital emergency room.**

What are the possible side effects of dexamethylphenidate hydrochloride extended-release capsules? Dexamethylphenidate hydrochloride extended-release capsules may cause serious side effects, including:

- see “What is the most important information I should know about dexamethylphenidate 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 doctor immediately.
- **circulation problems in fingers and toes** (peripheral vasculopathy, including Raynaud’s phenomenon):
 - o fingers or toes may feel numb, cool, painful
 - o fingers or toes may change color from pale, to blue, to redTell your doctor if you or your child have, numbness, pain, skin color change, or sensitivity to temperature in the fingers or toes.
- **Call your doctor right away if you have or your child has any signs of unexplained wounds appearing on fingers or toes while taking dexamethylphenidate hydrochloride extended-release capsules.**
- **slowing of growth (height and weight) in children**

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 dexmethylphenidate hydrochloride extended-release capsules?

- Store dexmethylphenidate 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 dexmethylphenidate hydrochloride extended-release capsules by a medicine take-back program at authorized collection sites, such as retail pharmacies, hospital or clinic pharmacies, and law enforcement locations. If no take-back program or authorized collector is available, mix dexmethylphenidate 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 (discard) dexmethylphenidate hydrochloride extended-release capsules in the household trash.
- **Keep dexmethylphenidate hydrochloride extended-release capsules and all medicines out of the reach of children.**

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

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. You can ask your pharmacist or doctor for information about dexmethylphenidate hydrochloride extended-release capsules that is written for healthcare professionals. Do not use dexmethylphenidate hydrochloride extended-release capsules for a condition for which it was not prescribed. Do not give dexmethylphenidate 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 dexmethylphenidate hydrochloride extended-release capsules?

Active ingredient: dexmethylphenidate 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.

Dispense with medication guide is also available at:
<http://www.granulesindia.com/U.S.ProductCatalog.php>

Manufactured By:

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

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