MEDICATION GUIDE

Dexmethylphenidate Hydrochloride Extended-Release Capsules CII

Read the Medication Guide that comes with dexmethylphenidate hydrochloride extended-release capsules before you or your child starts taking it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your doctor about your or your child’s treatment with dexmethylphenidate hydrochloride extended-release capsules.

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

The following have been reported with use of dexmethylphenidate 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 your 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

Children and Teenagers
   - 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.

3. Circulation problems in fingers and toes [Peripheral vasculopathy, including Raynaud’s phenomenon]: fingers or toes may feel numb, cool, painful, and/or may change color from pale, to blue, to red.
   - Tell your doctor if you have or your child has 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 dexmethylphenidate hydrochloride extended-release capsules.
What are dexmethylphenidate hydrochloride extended-release capsules?

Dexmethylphenidate hydrochloride extended-release capsules are a central nervous system stimulant 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.

Dexmethylphenidate hydrochloride extended-release capsules are a federally controlled substance (CII) because they 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 (or have a family history of) ever abused or been dependent on alcohol, prescription medicines or street drugs.

Who should not take dexmethylphenidate hydrochloride extended-release capsules?

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

- are very anxious, tense, or agitated.
- have an eye problem called glaucoma.
- have tics or Tourette’s syndrome, or a family history of Tourette’s syndrome. Tics are hard-to-control repeated movements or sounds.
- are taking or have taken within the past 14 days an anti-depression medicine called a monoamine oxidase inhibitor or MAOI.
- are allergic to anything in dexmethylphenidate hydrochloride extended-release capsules. See the end of this Medication Guide for a complete list of ingredients.

Dexmethylphenidate hydrochloride extended-release capsules should not be used in children less than 6 years old because it has not been studied in this age group.

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
- tics or Tourette’s syndrome
- seizures or have had an abnormal brain wave test (EEG)
- circulation problems in fingers or toes

Tell your doctor if you or your child is pregnant, planning to become pregnant, or breastfeeding.

Can dexmethylphenidate hydrochloride extended-release capsules be taken with other medicines?

Tell your doctor about all of the medicines that you or your child takes including prescription and nonprescription 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
- seizure medicines
- blood thinner medicines
- blood pressure medicines
- antacids
- cold or allergy medicines that contain decongestants

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

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

**How should dexmethylphenidate hydrochloride extended-release capsules be taken?**

- **Take dexmethylphenidate hydrochloride extended-release capsules exactly as prescribed.** Your doctor may adjust the dose until it is right for you or your child.
- Take dexmethylphenidate hydrochloride extended-release capsules once each day in the morning. This product is an extended-release capsule. It releases medicine into your body throughout the day.
- 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.
- From time to time, your doctor may stop dexmethylphenidate 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 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 takes too much dexmethylphenidate hydrochloride extended-release capsules or overdoses, call your doctor or poison control center right away, or get emergency treatment.**

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

See “**What is the most important information I should know about dexmethylphenidate hydrochloride extended-release capsules?**” for information on reported heart and mental problems.

**Other serious side effects include:**

- serious allergic reactions (symptoms can be difficulty breathing, swelling of the face, neck and throat, rashes and hives, fever)
- slowing of growth (height and weight) in children
- seizures, mainly in patients with a history of seizures
- painful and prolonged erections (priapism) have occurred with methylphenidate. If you or your child develop priapism seek medical help right away. Because of the potential for lasting damage, priapism should be evaluated by a doctor immediately.
- eyesight changes or blurred vision

**Common side effects include:**
Talk to your doctor if you or your child has side effects that are bothersome or do not go away.

This is not a complete list of possible side effects. Ask your doctor or pharmacist for more information.

**How should I store dexmethylphenidate hydrochloride extended-release capsules?**

- Store dexmethylphenidate hydrochloride extended-release capsules in a safe place at room temperature, 59°F to 86°F (15°C to 30°C).
- Keep dexmethylphenidate hydrochloride extended-release capsules and all medicines out of the reach of children.

**General information about dexmethylphenidate hydrochloride extended-release capsules**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. 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 condition. It may harm them and it is against the law.

This Medication Guide summarizes the most important information about dexmethylphenidate hydrochloride extended-release capsules. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about dexmethylphenidate hydrochloride extended-release capsules that was written for healthcare professionals. For more information about dexmethylphenidate hydrochloride extended-release capsules call 1-800-525-8747.

**What are the ingredients in dexmethylphenidate hydrochloride extended-release capsules?**

**Active Ingredient:** dexmethylphenidate hydrochloride

**Inactive Ingredients:** ammonio methacrylate copolymer, FD&C Blue #2 (5 mg, 15 mg, 25 mg, 35 mg, and 40 mg strengths), FDA/E172 yellow iron oxide (10 mg, 15 mg, 30 mg, 35 mg, and 40 mg strengths), gelatin, ink Tan SW-8010, methacrylic acid copolymer, polyethylene glycol, sugar spheres, talc, titanium dioxide, and triethyl citrate.

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

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