

**MEDICATION GUIDE**  
**RELEXXII® (RE-LEX-EE)**  
**(methylphenidate hydrochloride extended-release tablets)**  
**for oral use, CII**

**What is the most important information I should know about RELEXXII?**

**RELEXXII may cause serious side effects, including:**

- **Abuse, misuse, and addiction.** RELEXXII has a high chance for abuse and misuse and may lead to substance use problems, including addiction. Misuse and abuse of RELEXXII, 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 RELEXXII 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 RELEXXII and will monitor you or your child during treatment.
  - RELEXXII may lead to physical dependence after prolonged use, even if taken as directed by your healthcare provider.
  - Do not give RELEXXII to anyone else. See "What is RELEXXII?" for more information.
  - Keep RELEXXII in a safe place and properly dispose of any unused medicine. See "How should I store RELEXXII?"
  - 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 treatment with RELEXXII. 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 have any signs of heart problems such as chest pain, shortness of breath, or fainting during treatment with RELEXXII.

- **Increased blood pressure and heart rate.**

Your healthcare provider should check your or your child's blood pressure and heart rate regularly during treatment with RELEXXII.

- **Mental (psychiatric) problems, including:**

- new or worse behavior and thought problems
- new or worse bipolar illness
- new psychotic symptoms (such as hearing voices, or seeing or believing things that are not real) 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 during treatment with RELEXXII, especially hearing voices, seeing or believing things that are not real, or new manic symptoms.**

**What is RELEXXII?**

RELEXXII is a central nervous system (CNS) stimulant prescription medicine used for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in adults less than 65 years of age and children 6 years of age and older. RELEXXII may help increase attention and decrease impulsiveness and hyperactivity in people with ADHD.

It is not known if RELEXXII is safe and effective in children under 6 years of age.

RELEXXII has not been studied in adults older than 65 years of age.

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

**Do not take RELEXXII if: you or your child are:**

- allergic to methylphenidate or any of the ingredients in RELEXXII. See the end of this Medication Guide for a

complete list of ingredients in RELEXXII.

- taking, or have stopped taking within the past 14 days, a medicine called a monoamine oxidase inhibitor (MAOI).

**Before taking RELEXXII tell your healthcare provider about all your medical conditions, including if you or your child:**

- have heart problems, heart disease, heart defects, or high blood pressure
- have mental problems including psychosis, mania, bipolar illness, or depression, or a family history of suicide, bipolar illness, or depression
- have circulation problems in fingers and 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
- are pregnant or plan to become pregnant. It is not known if RELEXXII will harm the unborn baby.
  - **Pregnancy Exposure Registry:** There is a pregnancy registry for women who are exposed to RELEXXII during pregnancy. The purpose of the registry is to collect information about the health of women exposed to RELEXXII and their baby. If you or your child becomes pregnant during treatment with RELEXXII, talk to your healthcare provider about registering with the National Pregnancy Registry for Psychostimulants at 1-866-961-2388.
- are breastfeeding or plan to breastfeed. RELEXXII passes into breast milk. Talk to your healthcare provider about the best way to feed the baby during treatment with RELEXXII.

**Tell your healthcare provider about all of the medicines that you or your child take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

RELEXXII and some medicines may interact with each other and cause serious side effects. Sometimes the doses of other medicines will need to be changed during treatment with RELEXXII. Your healthcare provider will decide whether RELEXXII can be taken with other medicines.

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

- blood pressure medicines (anti-hypertensive)

Know the medicines that you take or your child take. Keep a list of your medicines with you to show your healthcare provider and pharmacist. **Do not start any new medicine during treatment with RELEXXII without first talking to your healthcare provider.**

**How should RELEXXII be taken?**

- Take RELEXXII exactly as prescribed by your healthcare provider.
- Your healthcare provider may change the dose or tell you to stop taking RELEXXII if needed.
- Take RELEXXII 1 time each day in the morning with or without food.
- Swallow RELEXXII whole with water or other liquids. Do not chew, crush, or divide the tablets. Tell your healthcare provider if you or your child cannot swallow RELEXXII whole. A different medicine may need to be prescribed.
- RELEXXII does not dissolve completely in the body after all the medicine has been released. You or your child may sometimes notice the empty tablet in a bowel movement. This is normal.

If you or your child take too much RELEXXII, 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 RELEXXII?**

**RELEXXII may cause serious side effects, including:**

- See "**What is the most important information I should know about RELEXXII?**"
- **Painful and prolonged erections (priapism).** Priapism that may require surgery has happened in males who take products that contain methylphenidate. **If you or your child develop priapism, get medical help right away.**
- **Circulation problems in fingers and toes (peripheral vasculopathy, including Raynaud's phenomenon):** Signs and symptoms may include:
  - 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 your fingers or toes, or if you or your child have any signs of unexplained wounds appearing on fingers or toes during treatment with RELEXXII.

- **Slowing of growth (height and weight) in children.** Children should have their height and weight checked often during treatment with RELEXXII. RELEXXII treatment may be stopped if your child is not growing or gaining weight.
- **Possible blockage of the intestine.** Because the RELEXXII tablet does not change in shape in the intestines (GI tract), RELEXXII should not be taken by people with severe intestinal problems (preexisting severe gastrointestinal narrowing).
- **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 RELEXXII.

**The most common side effects of RELEXXII in adults include:**

- decreased appetite
- dry mouth
- trouble sleeping (insomnia)
- dizziness
- irritability
- headache
- nausea
- anxiety
- weight loss
- increased sweating

**The most common side effects of RELEXXII in children 6 to 17 years of age was stomach pain.**

These are not all the possible side effects of RELEXXII.

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 RELEXXII?**

- Store RELEXXII at room temperature between 68°F to 77°F (20°C to 25°C).
- Store RELEXXII in a safe place, like a locked cabinet. Protect from light and moisture.
- Dispose of remaining, unused, or expired RELEXXII 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 RELEXXII 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 RELEXXII in the household trash. Visit [www.fda.gov/drugdisposal](http://www.fda.gov/drugdisposal) for additional information on disposal of unused medicines.

**Keep RELEXXII and all medicines out of the reach of children.**

**General information about the safe and effective use of RELEXXII.**

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

**What are the ingredients in RELEXXII?**

**Active Ingredient:** methylphenidate hydrochloride

**Inactive Ingredients:** cellulose acetate, colloidal silicon dioxide, ferrousferrous oxide, hypromellose, iron oxide black, lactose monohydrate, magnesium stearate, phosphoric acid, polyethylene glycol, polyethylene oxide, sodium chloride, succinic acid, titanium dioxide, and triacetin.

27 mg tablets contain: FD&C Yellow #6 Aluminum Lake, FD&C Blue #2 Aluminum Lake, FD&C Red #40 Aluminum Lake

45 mg tablets contain: FD&C Red #40 Aluminum Lake

54 mg tablets contain: FD&C Yellow #6 Aluminum Lake, FD&C Red #40 Aluminum Lake, FD&C Blue #2 Aluminum Lake

63 mg tablets contain: iron oxide red, iron oxide yellow

72 mg tablets contain: FD&C Blue #1 Aluminum Lake

**Distributed by:**

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For more information, go to [www.verticalpharma.com](http://www.verticalpharma.com) or call 1-800-444-5164

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

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