

MEDICATION GUIDE

XELSTRYM® (Zel' Strim)

(dextroamphetamine)
transdermal system, CII

What is the most important information I should know about XELSTRYM?

XELSTRYM may cause serious side effects, including:

- **Abuse, misuse, and addiction.** XELSTRYM has a high chance for abuse and misuse and may lead to substance use problems, including addiction. Misuse and abuse of XELSTRYM, other amphetamine containing medicines, and methylphenidate containing medicines, can lead to overdose and death. The risk of overdose and death is increased with higher doses of XELSTRYM 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 XELSTRYM and will monitor you or your child during treatment.
 - XELSTRYM may lead to physical dependence after prolonged use, even if taken as directed by your healthcare provider.
 - Do not give XELSTRYM to anyone else. See "**What is XELSTRYM?**" for more information.
 - Keep XELSTRYM in a safe place and properly dispose of any unused medicine. See "**How should I store XELSTRYM?**" 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 treatment with XELSTRYM. 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 XELSTRYM.
- **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 XELSTRYM.
- **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 XELSTRYM, especially hearing voices, seeing or believing things that are not real, or new manic symptoms.

What is XELSTRYM?

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

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

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

Do not use XELSTRYM if you or your child are:

- allergic to amphetamine products or any of the ingredients in XELSTRYM. See the end of the Medication Guide for a complete list of ingredients in XELSTRYM.
- taking or have taken within the past 14 days a medicine called a monoamine oxidase inhibitor (MAOI), including the antibiotic linezolid or the intravenous medicine called methylene blue.

Before using XELSTRYM, tell your healthcare provider about all 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 have a family history of suicide, bipolar illness, or depression
- have circulation problems in fingers and toes
- have kidney problems. Your healthcare provider may lower your dose.
- 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 XELSTRYM will harm the unborn baby.
 - There is a pregnancy registry for women who are exposed to XELSTRYM during pregnancy. The purpose of the registry is to collect information about the health of women exposed to XELSTRYM and their babies. If you or your child becomes pregnant during treatment with XELSTRYM, talk to your healthcare provider about registering with the National Pregnancy Registry for Psychiatric Medications at 1-866-961-2388 or visit online at <https://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/othermedications/>.
- are breastfeeding or plan to breastfeed. XELSTRYM passes into breast milk. You or your child should not breastfeed during treatment with XELSTRYM. Talk to your healthcare provider about the best way to feed the baby during treatment with XELSTRYM.

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

XELSTRYM may affect the way other medicines work and other medicines may affect how XELSTRYM works. Using XELSTRYM with other medicines may cause serious side effects. Sometimes the doses of other medicines will need to be changed while using XELSTRYM.

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

- selective serotonin reuptake inhibitors (SSRIs)
- medicines used to treat migraine headaches called triptans
- lithium
- tramadol
- buspirone
- serotonin norepinephrine reuptake inhibitors (SNRIs)
- tricyclic antidepressants
- fentanyl
- tryptophan
- St. John’s Wort

Your healthcare provider will decide whether XELSTRYM can be used with other medicines. **Do not start any new medicine during treatment with XELSTRYM without first talking to your healthcare provider.**

How should XELSTRYM be used?

- See the detailed “**Instructions for Use**” at the end of this XELSTRYM Medication Guide for information about the right way to apply, remove, and dispose of XELSTRYM.
- Your healthcare provider may change the dose if needed.
- **Apply 1 XELSTRYM patch at a time for not more than 9 hours.** Use only 1 XELSTRYM per 24 hours and change the site of application when applying a new patch.
- Apply the XELSTRYM patch 2 hours before the effect is needed and remove XELSTRYM within 9 hours after application.

If you or your child use too much XELSTRYM, call your healthcare provider or Poison Help line at 1-800-222-1222 or go to the nearest hospital emergency room right away.

What should I avoid while using XELSTRYM?

- Do not drive, operate heavy machinery, or do other potentially dangerous activities until you know how XELSTRYM affects you.
- After applying the XELSTRYM patch, avoid exposing the application site to direct external heat sources, such as hair dryers, heating pads or electric blankets, heat lamps, saunas, hot tubs, and heated water beds. Exposure to heat can cause too much medicine to pass into your body and cause serious side effects.

What are possible side effects of XELSTRYM?

XELSTRYM may cause serious side effects, including:

- See “**What is the most important information I should know about XELSTRYM**”

• **Slowing of growth (weight and height) in children.** Children should have their height and weight checked often during treatment with XELSTRYM. Your healthcare provider may stop the treatment with XELSTRYM if your child is not growing or gaining height or weight as expected.

• **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 your fingers or toes.

Call your healthcare provider right away if you or your child have any signs of unexplained wounds appearing on fingers or toes during treatment with XELSTRYM.

• **Serotonin Syndrome.** A potentially life-threatening problem called serotonin syndrome may happen when XELSTRYM is used with certain other medicines. See **“Before using XELSTRYM, tell your healthcare provider about all medical conditions, including if you or your child:”** Stop using XELSTRYM and call your healthcare provider or go to the nearest hospital emergency room right away if you or your child develop any of the following signs and symptoms of serotonin syndrome:

- agitation
- fast heartbeat
- flushing
- seizures
- coma
- sweating
- loss of coordination
- confusion
- dizziness
- tremors, stiff muscles, or muscle twitching
- seeing or hearing things that are not real (hallucination)
- changes in blood pressure
- high body temperature (hyperthermia)
- nausea, vomiting, diarrhea

• **Allergic skin rash (contact sensitization).** Stop using XELSTRYM and tell your healthcare provider right away if you or your child develop swelling or blisters at or around the application site. You may have a skin allergy to XELSTRYM. People who have skin allergies to XELSTRYM may develop an allergy to all amphetamine containing products, even amphetamine products that are taken by mouth.

• **Application site reactions** have happened with XELSTRYM while wearing the XELSTRYM patch, and after removal of the patch. Signs and symptoms of an application site reaction include, pain, itching, burning feeling, redness, discomfort, or swelling at the application site. Call your healthcare provider if you or your child develop any application site reactions that do not resolve on their own.

• **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 XELSTRYM.

The most common side effects of XELSTRYM include:

- decreased appetite
- trouble sleeping
- stomach pain
- nausea
- increased blood pressure
- headache
- muscle twitching (tics)
- vomiting
- irritability
- increased heart rate

These are not all the possible side effects of XELSTRYM.

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 XELSTRYM?

- Store XELSTRYM at room temperature between 68°F to 77°F (20°C to 25°C).
- Store XELSTRYM in a safe place, like a locked cabinet.
- Protect XELSTRYM from light and moisture.
- Keep XELSTRYM in their unopened pouches until you are ready to use them.
- Dispose of remaining unused or expired XELSTRYM by a medication 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, each unused patch should be removed from its individual pouch, separated from the protective liner, folded in half so the sticky sides stick together, and thrown away in a container with a lid in the household trash. **Do not** flush the XELSTRYM patch, pouch, or liner down the toilet. Visit www.fda.gov/drugdisposal for additional information on disposal of unused medicines.

Keep XELSTRYM and all medicines out of the reach of children.

General information about the safe and effective use of XELSTRYM.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use XELSTRYM for a condition for which it was not prescribed. Do not give XELSTRYM 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 XELSTRYM that is written for healthcare professionals.

What are the ingredients in XELSTRYM?

Active ingredient: dextroamphetamine

Inactive ingredients: acrylic adhesives, green ink, polyester/polyurethane backing, and polyester release liner

Manufactured by: Noven Pharmaceuticals, Inc., Miami, FL 33186
Xelstrym® is a registered trademark of Noven Therapeutics, LLC.
For more information, go to www.xelstrym.com or call 1-800-455-8070.

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

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