Individualize treatment for adult patients with ADHD

Xelstrym®
(dextroamphetamine) CII
transdermal system
4.5mg/9 hours 9mg/9 hours 13.5mg/9 hours 18mg/9 hours

Dosing and Administration Guide

- **The first and only FDA-approved amphetamine transdermal patch[1]**
- **Work with your patients to determine when to apply and when to remove the patch**

Patch not actual size.

XELSTRYM should be removed within 9 hours. Dose titration and final dosage should be individualized depending on clinical response and tolerability.[1]

INDICATION AND LIMITATIONS OF USE

XELSTRYM (dextroamphetamine) transdermal system, CII is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in adult and pediatric patients 6 years and older. Pediatric patients younger than 6 years of age experienced more long-term weight loss than patients 6 years and older.

IMPORTANT SAFETY INFORMATION

WARNING: ABUSE, MISUSE, AND ADDICTION

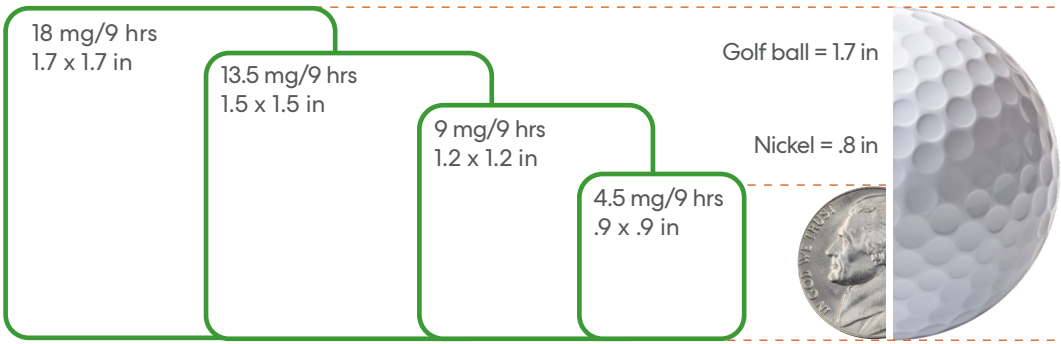
XELSTRYM has a high potential for abuse and misuse, which can lead to the development of a substance use disorder, including addiction. Misuse and abuse of CNS stimulants, including XELSTRYM, can result in overdose and death, and this risk is increased with higher doses or unapproved methods of administration, such as snorting or injection.

Before prescribing XELSTRYM, assess each patient's risk for abuse, misuse, and addiction. Educate patients and their families about these risks, proper storage of the drug, and proper disposal of any unused drug. Throughout XELSTRYM treatment, reassess each patient's risk of abuse, misuse, and addiction and frequently monitor for signs and symptoms of abuse, misuse, and addiction.

Please see Important Safety Information throughout and click here for full Prescribing Information, including BOXED WARNING.

With dosing that allows you to individualize your patients' treatment based on efficacy and tolerability

Four dosing strengths provide flexible titration[1]



Patches, US nickel, and golf ball shown at actual size.

PRIOR TO INITIATING XELSTRYM[1]

- **Assess for the presence of cardiac disease[1]**
- **Assess the risk of abuse prior to prescribing and monitor for signs of abuse and dependence while on therapy[1]**
- **Maximum doses for compromised patients**
  - Severe renal impairment: Maximum dose is 13.5 mg/9 hours[1]
  - End stage renal disease: Maximum dose is 9 mg/9 hours[1]

IMPORTANT SAFETY INFORMATION (CONTINUED)

CONTRAINDICATIONS

- Known hypersensitivity to amphetamine products or other components in XELSTRYM. Anaphylactic reactions, Stevens-Johnson Syndrome, angioedema, and urticaria have been observed.
- Use with monoamine oxidase inhibitors (MAOIs), or within 14 days of stopping MAOIs (including linezolid or intravenous methylene blue) due to increased risk of hypertensive crisis.

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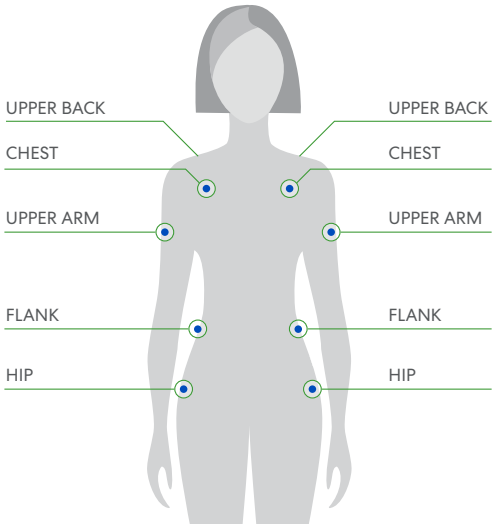
Recommended starting dose for adults: 9 mg/9 hrs[1]

- Adult dosage may be adjusted up to a maximum recommended dose of 18 mg/9 hrs
- Recommended starting dose for children and adolescents, aged 6 to 17 years: 4.5 mg/9 hrs
  - Dosage may be adjusted in weekly increments of 4.5 mg up to a maximum recommended dose of 18 mg/9 hrs
- Dose titration and final dosage should be individualized depending on clinical response and tolerability
- XELSTRYM should be removed within 9 hours after application

10 Application wear sites[1]

- Usage: one patch daily (per 24 hours)
- Do not wear the patch for more than 9 hours
- Application site should be changed when a new patch is applied



IMPORTANT SAFETY INFORMATION (CONTINUED)

WARNINGS AND PRECAUTIONS

Risks to Patients with Serious Cardiac Disease: Avoid XELSTRYM use in patients with known structural cardiac abnormalities, cardiomyopathy, serious cardiac arrhythmia, coronary artery disease, or other serious cardiac diseases. Sudden death has been reported in patients with structural cardiac abnormalities or other serious cardiac disease who were treated with CNS stimulants at the recommended ADHD dosage.

Increased Blood Pressure and Heart Rate: CNS stimulants cause an increase in blood pressure (mean increase about 2 to 4 mm Hg) and heart rate (mean increase about 3 to 6 bpm). Monitor all patients for potential tachycardia and hypertension.

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When can my patients wear the patch?[1]

	YES	AVOID
Showering*	✓	
Bathing*	✓	
Swimming*	✓	
Activities that cause sweating†	✓	
Direct heat‡		✗

*Patients should check to see if the patch has become loose after bathing, showering, or swimming.

†Patients should check their patch fit if they sweat excessively.

‡After applying XELSTRYM, patients should 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 their body and cause serious side effects.

Click here to watch our IFU video

IMPORTANT SAFETY INFORMATION (CONTINUED)

WARNINGS AND PRECAUTIONS (CONTINUED)

Psychiatric adverse reactions: *Exacerbation of Pre-existing Psychosis* : May exacerbate symptoms of behavior disturbance and thought disorder in patients with a pre-existing psychotic disorder. *Induction of a Manic Episode in Patients with Bipolar Disorder* : May induce a mixed/manic episode in patients. Prior to initiating XELSTRYM treatment, screen for risk factors for developing a manic episode (e.g., comorbid or history of depressive symptoms, or a family history of suicide, bipolar disorder, and depression). *New Psychotic or Manic Symptoms* : At recommended doses, may cause psychotic or manic symptoms (e.g., hallucinations, delusional thinking, or mania) in patients with no prior history of psychotic illness or mania. Discontinue XELSTRYM if symptoms occur.

Long-Term Suppression of Growth in Pediatric Patients: CNS stimulants have been associated with weight loss and slowing of growth rate in pediatric patients. Closely monitor growth (weight and height). Treatment may need to be interrupted in pediatric patients not growing or gaining weight as expected. XELSTRYM is not approved for use in pediatric patients below 6 years of age.

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IMPORTANT SAFETY INFORMATION (CONTINUED)

WARNINGS AND PRECAUTIONS (CONTINUED)

Peripheral Vasculopathy, including Raynaud's Phenomenon: Stimulants, including XELSTRYM, are associated with peripheral vasculopathy, including Raynaud's phenomenon. Signs and symptoms are usually intermittent and mild; very rare sequelae include digital ulceration and/or soft tissue breakdown. Careful observation for digital changes is necessary during treatment with stimulants. Further evaluation including rheumatology referral, may be appropriate for certain patients.

Serotonin Syndrome: Risk is increased when XELSTRYM is co-administered with serotonergic agents (e.g., SSRIs, SNRIs, triptans), and with CYP2D6 inhibitors. If it occurs, discontinue XELSTRYM and initiate supportive treatment.

Contact Sensitization: Use of XELSTRYM may lead to contact sensitization. Discontinue XELSTRYM if contact sensitization is suspected.

Application Site Reactions: During wear time or immediately after removal of XELSTRYM, local skin reactions such as pain, pruritus, burning sensation, erythema, discomfort, edema, and/or swelling were reported. Select a different application site each day to minimize skin reactions.

External Heat: Avoid exposing XELSTRYM to direct external heat sources during wear because both the rate and extent of absorption are increased.

Motor and Verbal Tics, and Worsening of Tourette's Syndrome: Before initiating XELSTRYM, assess the family history and clinically evaluate patients for tics or Tourette's syndrome. Regularly monitor XELSTRYM-treated patients for the emergence or worsening of tics or Tourette's syndrome, and discontinue treatment if clinically appropriate. CNS stimulants, including methylphenidate, have been associated with the onset or exacerbation of motor and verbal tics. Worsening of Tourette's syndrome has also been reported.

ADVERSE REACTIONS

Most common adverse reactions (incidence ≥2% and greater than the rate for placebo) in pediatric patients 6 to 17 years treated with XELSTRYM were: decreased appetite, headache, insomnia, tic, abdominal pain, vomiting, nausea, irritability, increased blood pressure, and increased heart rate.

Most common adverse reactions (incidence of ≥5% and a rate at least twice placebo) in adults treated with lisdexamfetamine were: decreased appetite, insomnia, dry mouth, diarrhea, nausea, and anxiety.

PREGNANCY AND LACTATION

XELSTRYM may cause fetal harm. Breastfeeding is not recommended during XELSTRYM treatment.

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For adult patients with ADHD

Prescribe XELSTRYM

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(dextroamphetamine) CII
transdermal system
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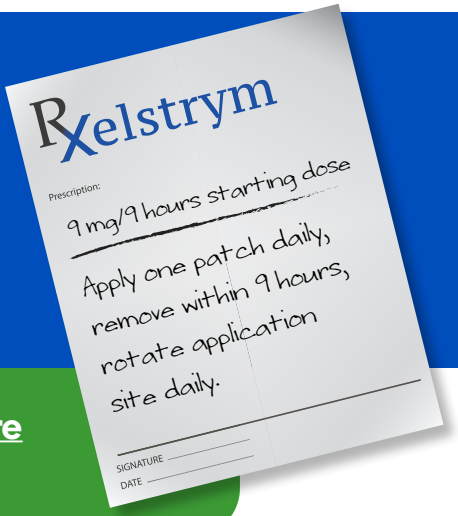
- The first and only non-oral amphetamine ADHD treatment[1]
- Together, you and your patients can determine when to apply and when to remove the patch



For more information, click here to visit xelstrymhcp.com

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Reference: 1. XELSTRYM (dextroamphetamine) transdermal system, CII [package insert]. Miami, FL. Noven Therapeutics, LLC. October 2023.

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