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

The Mindful Patch™ app
An optional companion tool designed to support transdermal treatment with XELSTRYM®.

Help patients *start and stay on track* with their transdermal treatment plan

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. The use of XELSTRYM is not recommended in pediatric patients younger than 6 years of age because they had higher plasma exposure and a higher incidence of adverse reactions (e.g., weight loss) than patients 6 years and older at the same dosage.

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.

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.

Please see additional Important Safety Information on page 3 and full Prescribing Information, including the BOXED WARNING.

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Help patients get started and stay on track with their XELSTRYM® treatment

The Mindful Patch optional companion app helps your patients manage their time, their way. By working with your patients to determine when to apply and when to remove the patch, patients can tailor their patch application and removal reminders to align with their individual schedules.

The Mindful Patch app gives your patients instant access to a variety of transdermal treatment support tools, including:

Educational resources and videos

Access a variety of helpful patient education and support resources through the app:

- Instructions for starting—and staying on track with—XELSTRYM
- Patch application and removal instructions
- Patient education video

Personalized medication schedule and reminders

Work with your patients to create a patch application and removal schedule that aligns to their individual lifestyle and changing daily routines:

- Customizable medication schedule reminders can help keep their transdermal treatment plan on track

Copay savings opportunities

Register for copay savings directly through the Mindful Patch app:

- Partner pharmacy savings offers
- Savings program enrollment
- Prescription delivery options (if available)
- SMS refill reminders

Pharmacy locator tool

Locate partner pharmacies through the Mindful Patch app:

- Find pharmacy locations in their area
- Add Noven partner pharmacies to their mobile contacts list
- Access assistance with XELSTRYM prescriptions

ADHD and wellbeing tracking

With tracking of factors related to their ADHD and overall wellbeing, the Mindful Patch app can help provide a selected view of:

- Patch application and removal trends
- Approved application site rotations
- ADHD factors and wellbeing
- Optional integrated Apple and Android health data

User-friendly data dashboard

- Patch application and removal trends can be exported and shared with healthcare providers

Download the Mindful Patch app

Download on the App Store
Download via the Apple store

GET IT ON Google Play
Download via the Google app store

IMPORTANT SAFETY INFORMATION (continued)

CONTRAINDICATIONS

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Resources available within the Mindful Patch app can also be accessed from the XELSTRYM patient website.

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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.

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: XELSTRYM is not approved for use and is not recommended in pediatric patients below 6 years of age. 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.

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.

USE IN SPECIFIC POPULATIONS

Pregnancy and Lactation: XELSTRYM may cause fetal harm. Breastfeeding is not recommended during XELSTRYM treatment.

Pediatric Use: The safety and effectiveness of XELSTRYM have not been established in pediatric patients below the age of 6 years.

Please see full Prescribing Information, including the BOXED WARNING.

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