

Instructions for Use

**Xelstrym**[®]

(dextroamphetamine) 
transdermal system

4.5mg/9 hours 9mg/9 hours 13.5mg/9 hours 18mg/9 hours

Read this *Instructions for Use* guide before you start using XELSTRYM and each time you get a refill.

There may be new information. This information does not take the place of talking to your healthcare provider about your or your child's medical condition or treatment.

Please read Important Safety Information on pages 17-22 and [click here](#) for Medication Guide and Full Prescribing Information, including the BOXED WARNING.

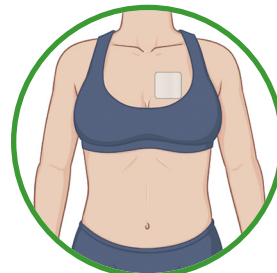
Important Information You Need to Know Before Applying XELSTRYM®

- Wear **only one patch** at a time
- A new patch must be applied every day
- Do not wear XELSTRYM for more than **9 hours**. Use only **1 patch per day** (per 24 hours)
- When you apply a **new patch**, choose a **different application site** from the one used the previous day to reduce the chance of skin reactions
- **Avoid touching the sticky side of XELSTRYM** with your fingers. **If you accidentally touch the sticky side of the patch, immediately wash your hands with soap and water** to remove any medicine that may have stuck to your fingers. **Do not** use hand sanitizer in place of soap and water
- **Avoid** exposing the application site to direct external heat sources, such as heating pads or electric blankets, heat lamps, saunas, hot tubs, heated water beds, and hair dryers
- Check the patch after bathing, showering, or swimming
- If the patch falls off or the edges lift, follow the instructions in Step 7

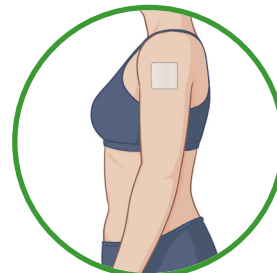
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Preparing to Apply the XELSTRYM Patch

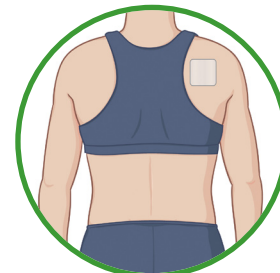
STEP 1: Choose 1 application site, on either the left or right side, to apply 1 patch. The recommended application sites include:



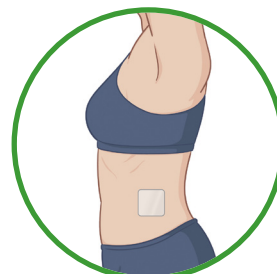
Chest



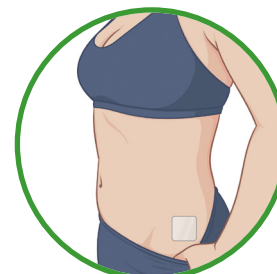
Upper arm



Upper back



Flank



Hip

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Preparing to Apply the XELSTRYM® Patch (cont'd)

STEP 1: Choose 1 application site (cont'd)

- **Do not** apply a patch to any other site
- **Avoid areas of tight clothing**, such as waistbands or straps
- Choose a **different application site** from the one used the previous day
- Check the expiration date before applying the patch

STEP 2: Check the skin where the patch will be applied

Make sure it is:

- **Not damaged** (cut, scraped, burned), irritated (rashes), or has any other problems
- **Cleaned** with soap and water (not an alcohol-based product), dry (not wet), with no powder, oil, lotion, or gel
- **Hairless or nearly hairless**. Applying the patch to a hairy application site could result in the patch falling off
 - If there is hair at the application site, **do not shave** application site. **Use scissors to clip hair** as close to the skin as possible

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How to Apply the Patch

STEP 3: When you are ready to apply your patch

- Do not open the pouch until you are ready to apply the patch
- Using scissors, carefully cut along the right side of the pouch. Start at the dashed line marked on the pouch as “**Step 1. Cut This Side**” and cut along the entire length of the pouch, through the bar code (see Figure A)
- Next, carefully cut the top of the pouch along the dashed line marked on the pouch as “**Step 2. Cut Across Top**” (see Figure B)
- Gently remove the contents of the pouch and throw away the slip liners (additional pieces of clear plastic) above and below the patch (see Figure C)



Figure A



Figure B

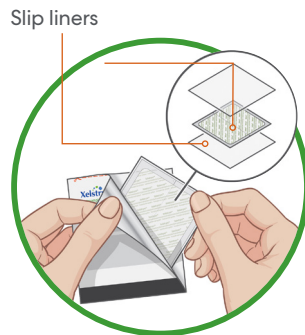


Figure C

STEP 4: Applying your patch

- Gently peel away half of the clear plastic liner.
Avoid touching the sticky side with your fingers (see Figure D)
- If you accidentally touch the sticky side of the patch, wash your hands with soap and water (do not use hand sanitizer) to remove any medicine that might be stuck to your hands

NOTE: Do not use the patch if it is cut or damaged. Apply the patch right away after removing it from the pouch.

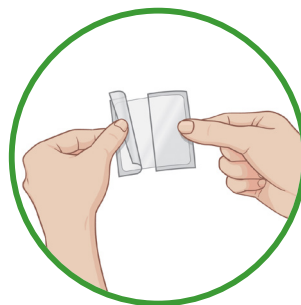


Figure D

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How to Apply the Patch (cont'd)

STEP 5: Applying your patch

- Apply the sticky side of the patch to the application site you selected and **smooth it down** (see Figure E)
- Hold the edge of the remaining protective liner, slowly peel it off, and smooth the patch down (see Figure F)
- Press the patch firmly with the palm of your hand (see Figure G) and **smooth the patch** down to make sure it sticks well to your skin
- The XELSTRYM® patch should not be applied or reapplied with dressings, tape, or other adhesives



Figure E

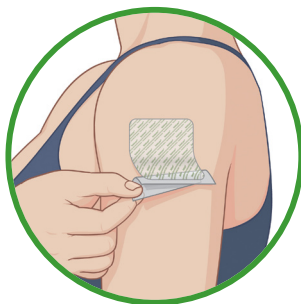


Figure F



Figure G

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STEP 6: Wash your hands with soap and water

- **Do not use hand sanitizer** in place of soap and water
- Take note of when you applied the patch so you know when to remove it



It's Important to Regularly Check Your Patch Throughout the Day

STEP 7: Check the patch regularly

Check XELSTRYM® regularly during the day to make sure it is completely sticking to the application site. Also check the patch when:



Using the bathroom



After sleeping



After bathing, showering,
or swimming



Changing clothes or undressing



Sweating a lot

If the edges have lifted, smooth the patch down on the skin and press firmly with the palm of your hand. The XELSTRYM patch should not be reapplied with dressings, tape, or other adhesives.

- If the patch falls off, do not reapply the same patch (fold the patch in half and throw it away per instructions in Step 9)
- You may reapply a new patch to a different application site
- **Total wear time for the first patch that fell off and the second replacement patch should not exceed a total of 9 hours in one day (24 hours)**

Parents or caregivers of children prescribed XELSTRYM should instruct the child to tell an adult if the patch becomes loose or falls off

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Note the Time You Applied the Patch

STEP 8: Keep track of the time

Keep track of when you put the patch on so you know when to remove it. **Work with your doctor to determine when to apply and when to remove the patch.**

- This table can be used to help you figure out different schedules for a 9-hour wear time
 - For example, if you put the patch on at 6 AM you should remove the patch no later than 3 PM the same day

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XELSTRYM Application Schedule for a 9-hour Wear Time

If you put the patch on at:	On the same day, remove the patch no later than:
6:00 AM	3:00 PM
7:00 AM	4:00 PM
8:00 AM	5:00 PM
9:00 AM	6:00 PM
10:00 AM	7:00 PM
11:00 AM	8:00 PM
12:00 PM	9:00 PM

When You Are Ready to Remove Your Patch

STEP 9: After no more than 9 hours, remove XELSTRYM®

Fold it in half so that the sticky sides stick together (see Figure H) to avoid accidental exposure to medicine. If any adhesive (glue) remains on your skin after you remove the patch, apply an **oil-based product or wash with water and soap** to remove the excess adhesive from your skin.

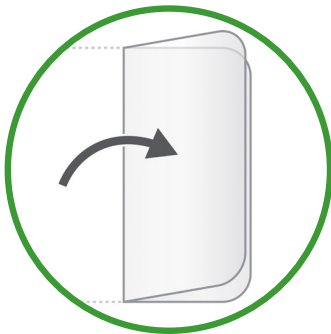


Figure H

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STEP 10: Throw the patch away

Throw away the used patch in a **container with a lid** right away (see Figure I)

STEP 11: Wash your hands with soap and water after throwing the patch away

- **Do not** use hand sanitizer in place of soap and water

Disposing of Unused XELSTRYM:

- Dispose of remaining unused or expired XELSTRYM by a medication take-back program at a US 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.

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Figure I

How Do I Store the XELSTRYM® Patch?



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 the unopened pouches until you are ready to apply



Keep XELSTRYM and all medicines out of the reach of children

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IMPORTANT SAFETY INFORMATION

What is XELSTRYM?

XELSTRYM is a central nervous system stimulant prescription medicine used for the treatment of Attention-Deficit Hyperactivity Disorder (ADHD) in adults and children 6 years and older. XELSTRYM may help increase attention and decrease impulsiveness and hyperactivity in adults and children 6 years of age and older with ADHD. XELSTRYM is not recommended for use in children under 6 years of age with ADHD.

IMPORTANT SAFETY INFORMATION

Abuse, misuse, and addiction: 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 sell or give your XELSTRYM to anyone else because it may cause death or harm to them and it is against the law. Tell your healthcare provider (HCP) if you or your child have ever abused or been dependent on alcohol, prescription medicines, or street drugs.

Do not use XELSTRYM if you or your child are:

- Allergic to amphetamine 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.

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IMPORTANT SAFETY INFORMATION (CONTINUED)

XELSTRYM can cause serious side effects, including:

- **Risks for people with serious heart disease.** Sudden death has happened in people who have heart defects or other serious heart disease. Your HCP should check you or your child carefully for heart problems before starting treatment with XELSTRYM. Tell your HCP if you or your child have any heart problems, heart disease, or heart defects. **Call your HCP 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 HCP should check you 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 HCP about any mental problems you or your child have or about a family history of suicide, bipolar illness, or depression. **Call your HCP right away if you or your child have any new or worsening mental symptoms or problems during treatment with XELSTRYM, especially hearing, seeing or believing things that are not real, or new manic symptoms.**

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IMPORTANT SAFETY INFORMATION (CONTINUED)

- **Slowing of growth (height or weight) in children.** Children should have their height and weight checked often while on XELSTRYM. Your HCP may stop 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, or painful. Fingers or toes may change color from pale, to blue, to red. Tell your HCP if you or your child have any numbness, pain, skin color change, or sensitivity to temperature in the fingers or toes. **Call your HCP right away if you or your child have any signs of unexplained wounds appearing on fingers or toes while using XELSTRYM.**
- **Serotonin syndrome.** Symptoms such as agitation, fast heartbeat, flushing, seizures, coma, sweating, loss of coordination, confusion, dizziness, tremors, stiff muscles, muscle twitching, seeing or hearing things that are not real (hallucinations), changes in blood pressure, high body temperature (hyperthermia), nausea, vomiting, or diarrhea may occur. Stop using XELSTRYM and call your HCP or go to the emergency room if symptoms occur. Serotonin syndrome may occur if XELSTRYM is taken with certain medicines and may be life-threatening.
- **Allergic skin rash (contact sensitization).** Stop using XELSTRYM and tell your HCP right away if you or your child develop swelling or blisters at or around the application site.



IMPORTANT SAFETY INFORMATION (CONTINUED)

XELSTRYM can cause serious side effects, including: (continued)

- **Application site reactions.** Reactions have happened while wearing XELSTRYM and after removing it. Symptoms include pain, itching, burning feeling, redness, discomfort, or swelling at the application site. Call your HCP 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 HCP if you or your child get any new or worsening tics or worsening Tourette's syndrome during treatment with XELSTRYM.

Before taking XELSTRYM tell your HCP about all the medications you take and any medical conditions including if you:

- Are pregnant or plan to become pregnant. It is not known if XELSTRYM may harm your 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. For more information on registering with the National Pregnancy Registry for Psychiatric Medications call 1-866-961-2388 or visit online at <https://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/othermedications/>.

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IMPORTANT SAFETY INFORMATION (CONTINUED)

Before taking XELSTRYM tell your HCP about all the medications you take and any medical conditions including if you: (continued):

- Are breastfeeding or plan to breastfeed. XELSTRYM can pass into your milk. Do not breastfeed while taking XELSTRYM. Talk to your doctor about the best way to feed your baby if you take XELSTRYM.

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.
- Avoid exposing the application site to direct external heat sources such as hair dryers, heating pads, electric blankets, heat lamps, saunas, hot tubs, and heated water beds, as exposure to heat can cause too much medicine to pass into your body and cause serious side effects.

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IMPORTANT SAFETY INFORMATION (CONTINUED)

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

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You are encouraged to report negative side effects of prescription drugs to FDA. Visit <http://www.fda.gov/medwatch> or call 1-800-FDA-1088.



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