

INSTRUCTIONS FOR USE

XELSTRYM® (Zel' Strim) (dextroamphetamine) transdermal system, CII

This Instructions for Use contains information on how to apply, remove, and dispose of XELSTRYM transdermal system (patch).

XELSTRYM transdermal system (patch) is for use on skin only.

Read this Instructions for Use 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.

XELSTRYM is supplied in cartons containing 30 patches. Each patch is sealed in a pouch protecting it until you are ready to apply it.

Important information you need to know before applying XELSTRYM:

- Wear **only 1 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 such as irritation, discomfort or pain at the application site.
- **Avoid touching the sticky side of XELSTRYM** with your fingers. **If you accidentally touch the sticky side of the patch, wash your hands right away with soap and water** to remove any potential 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 to see if the patch has become loose after bathing, showering or swimming.
- If the patch falls off:
 - **Do not reapply the same patch. Fold the patch in half so that the sticky sides are together and throw away the patch as instructed below in Steps 5 to 7.**
 - You should choose a different application site and apply a new patch.
 - The total wear time for the first patch that fell off and the second replacement patch should not total more than 9 hours in 1 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.

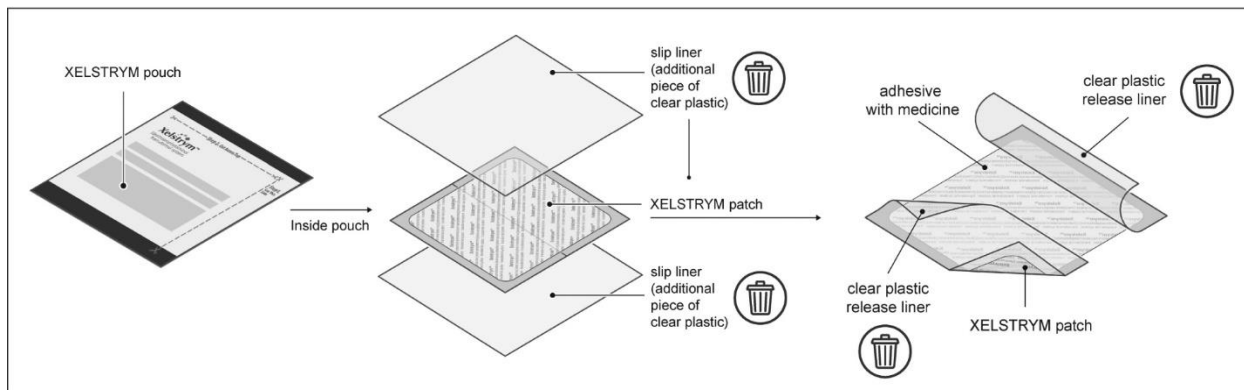


Figure A (not to scale).

Applying XELSTRYM:

Step 1: Select the patch application site (see Figure B).

- 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 (sides of the waist)
 - hip
- **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 when you apply a **new patch**.
- Check the expiration date before applying the patch.

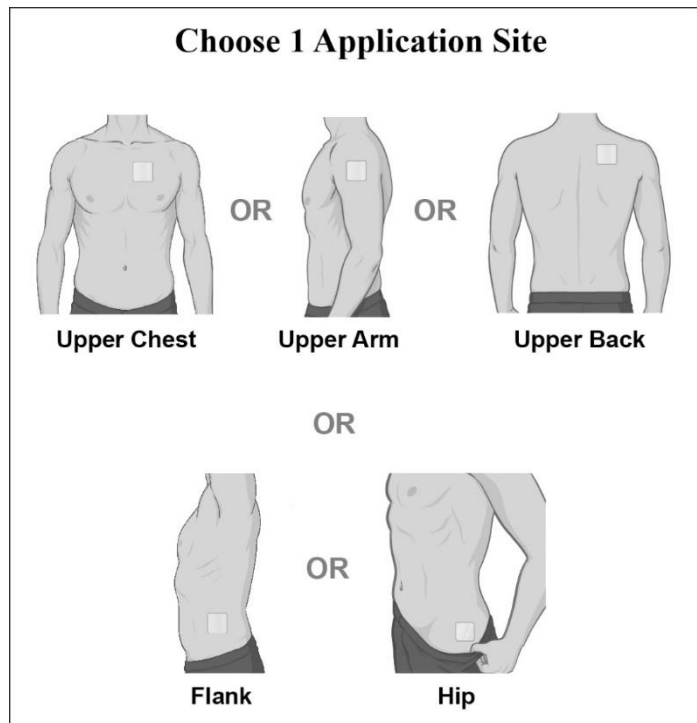


Figure B

Step 2: Check the skin where XELSTRYM will be applied. Make sure it is:

- **Not damaged** (cut, scraped, burned), irritated (rashes), or has any other skin 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 patch application site, **do not shave** the application site. **Use scissors to clip hair** as close to the skin as possible.

Step 3: Applying XELSTRYM

- 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 C).
- Next, carefully cut the top of the pouch along the dashed line marked on the pouch as “Step 2. Cut Across Top” (see Figure D).
- 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 A, Figure E).
 - **Do not** use the patch if it is cut or damaged

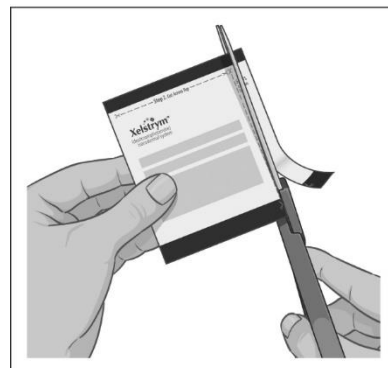


Figure C

- Apply the patch right away after removing it from the pouch

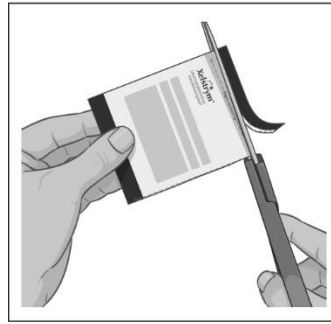


Figure D

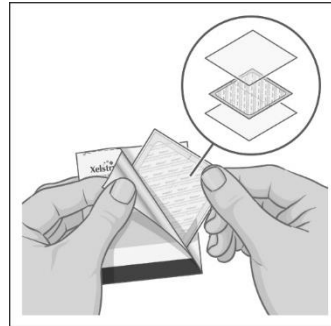


Figure E

- Gently peel away half of the clear plastic liner. **Avoid touching the sticky side with your fingers** (see **Figure F**).
- Apply the sticky side of the patch to the application site you selected and **smooth it down** (see **Figure G**).

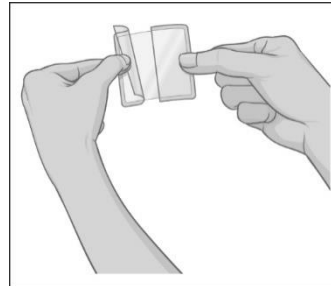


Figure F

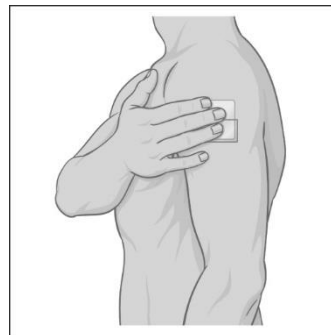


Figure G

- Hold the edge of the remaining protective liner, slowly peel it off and smooth the patch down (see **Figure H**).
- Press the patch firmly with the palm of your hand (see **Figure I**).
 - **Smooth the patch** to make sure it sticks well to your skin.

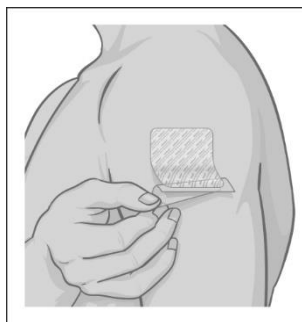


Figure H

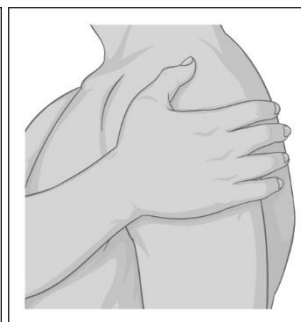


Figure I

XELSTRYM patch should not be applied or reapplied with dressings, tape, or other adhesives.

- **Wash your hands** with soap and water after applying the patch (see **Figure J**).
- **Do not use hand sanitizer** in place of soap and water.

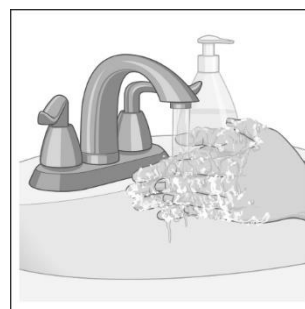


Figure J

Step 4: 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
- undressing or changing clothes
- if sweating a lot
- If patch edges lift, smooth the patch down on the skin and press firmly with the palm of your hand. 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 so that the sticky sides are together and throw away the patch as instructed below in **Steps 5 to 7**. You may apply a new patch to a different application site. **The total wear time for the first patch that fell off and the second replacement patch should not be more than a total of 9 hours in 1 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.

XELSTRYM Application Schedule for 9 Hour Wear Time:

If you put the patch on at:	On the same day, remove the patch no later than:
6:00 a.m.	3:00 p.m.
7:00 a.m.	4:00 p.m.
8:00 a.m.	5:00 p.m.

9:00 a.m.	6:00 p.m.
10:00 a.m.	7:00 p.m.
11:00 a.m.	8:00 p.m.
12:00 p.m.	9:00 p.m.

Removing and Disposing Used XELSTRYM:

Step 5: After **9 hours**, remove XELSTRYM and **fold it in half** so that the sticky sides stick together (see **Figure K**) 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 water and soap** to the skin to remove the glue.

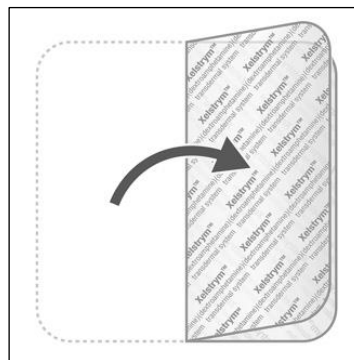


Figure K

Step 6: Throw away the used patch in a **container with a lid** right away (see **Figure L**).



Figure L

Step 7: Wash your hands with soap and water after throwing the patch away (see **Figure M**).

Do not use hand sanitizer in place of soap and water.



Figure M

Storing 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.
- **Keep XELSTRYM and all medicines out of the reach of children.**

Disposing of Unused XELSTRYM:

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.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

Revised: 10/2023

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