

INSTRUCTIONS FOR USE TAKHZYRO® (tak-ZYE-roe) (lanadelumab-flyo) injection, for subcutaneous use single-dose 1 mL prefilled syringe

This Instructions for Use contains information on how to inject TAKHZYRO. Please make sure to read, understand, and follow the Instructions for Use before injecting TAKHZYRO.

A healthcare provider should show you how to prepare and inject TAKHZYRO properly before you use it for the first time. Contact your healthcare provider if you have any questions.

Important information:

- TAKHZYRO is a ready to use prefilled syringe (**Figure A**) for injection under the skin (subcutaneous) to be given to children by their healthcare provider or caregiver. **Self-injection is not recommended in children (2 to less than 12 years of age).**
- Each TAKHZYRO prefilled syringe contains one 150 mg/1 mL dose. **The TAKHZYRO prefilled syringe is for single use only.**

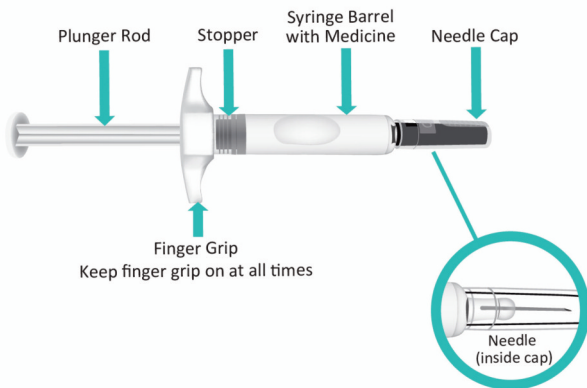


Figure A: TAKHZYRO prefilled syringe

Storing TAKHZYRO:

- Store the TAKHZYRO prefilled syringe in the refrigerator at 36°F to 46°F (2°C to 8°C). **Do not freeze.**
- Store the TAKHZYRO prefilled syringe in the original carton to protect it from light.
- Throw away (discard) the TAKHZYRO prefilled syringe if it has been kept out of the refrigerator, frozen, or not kept in the original carton protected from light.
- Do not** shake the TAKHZYRO prefilled syringe. **Keep the TAKHZYRO prefilled syringe and all medicines out of the reach of children.**

Step 1: Prepare for your injection

- Gather an alcohol swab, cotton ball or gauze pad, adhesive bandage, and sharps disposal container (**Figure B**) and place the supplies on a clean, flat, surface in a well-lit area. These supplies are not included in the TAKHZYRO carton.

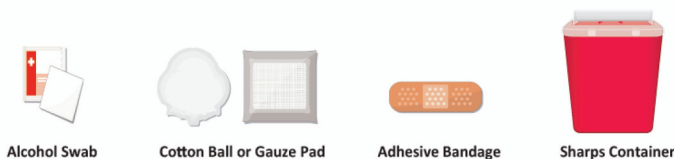


Figure B: Supplies

- Remove the TAKHZYRO prefilled syringe carton from the refrigerator 15 minutes before injecting.
 - Do not** use if the seal on the carton is open or broken.
 - Your medicine is sensitive to warm temperatures. **Do not** use heat sources such as a microwave or hot water to warm your TAKHZYRO prefilled syringe.



- Open the carton. Hold the syringe barrel and remove the TAKHZYRO prefilled syringe from the tray (**Figure C**).
 - Do not** remove the needle cap until you are ready to inject.
 - Do not** touch or push the plunger rod until you are ready to inject.



Figure C: Remove prefilled syringe

- Wash your hands with soap and water (**Figure D**). Dry your hands completely.
 - Do not** touch any surface or body part after washing your hands before the injection.



Figure D: Wash hands

- Check the expiration date (EXP)** on the syringe barrel (**Figure E**).
 - Do not** use the TAKHZYRO prefilled syringe if the expiration date has passed. If the TAKHZYRO prefilled syringe is expired throw it away (discard) in a sharps container and contact your healthcare provider.



Figure E: Location of expiration date

- Inspect** the TAKHZYRO prefilled syringe for any damage. The medicine inside the syringe barrel should be colorless to slightly yellow (**Figure F**).
 - Do not** use the TAKHZYRO prefilled syringe if the syringe is damaged or cracked.
 - Do not** use the TAKHZYRO prefilled syringe if the medicine is discolored, cloudy, or has flakes or particles in it.
 - You may see air bubbles in the TAKHZYRO prefilled syringe. This is normal and will not affect your dose.

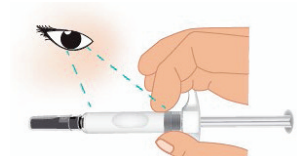


Figure F: Inspect the prefilled syringe

If you cannot use the prefilled syringe, contact your healthcare provider.

Step 2: Select and prepare injection site

- a. TAKHZYRO should be injected by a healthcare provider or caregiver into the following sites only (**Figure G**):
- stomach area (abdomen)
 - thighs
 - upper arms
 - **Do not** inject into an area where the skin is irritated, red, bruised, or infected.
 - The area you choose for injection should be at least 2 inches away from any scars or belly button (navel).

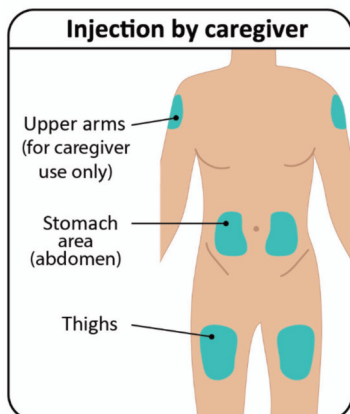


Figure G: Injection sites

Important:

Rotate injection sites to keep skin healthy. Each new injection should be given at least 1 inch from the last site you used.

- b. Clean the injection site with an alcohol swab and allow it to dry completely (**Figure H**).
- **Do not** fan or blow on the clean site.
 - **Do not** touch the clean site again before giving your injection.

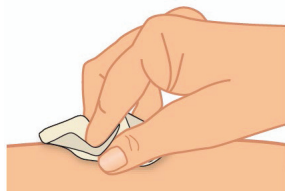


Figure H: Clean injection site

- c. Firmly hold the middle of the TAKHZYRO prefilled syringe with one hand, and with the other hand, gently pull the needle cap straight off (**Figure I**).

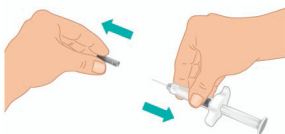


Figure I: Remove needle cap

- **Do not** touch or push the plunger rod until you are ready to inject.
- **Do not** use the TAKHZYRO prefilled syringe if it has been dropped without the needle cap on.
- **Do not** use the TAKHZYRO prefilled syringe if the needle looks damaged or bent.
- **Do not** touch the needle or allow the needle to touch anything.

You may see air bubbles, this is normal. **Do not** try to remove the air bubbles.

- d. Throw away the needle cap in your trash or in your sharps container.
- **Do not** recap the needle to avoid a needle-stick injury.

Step 3: Inject TAKHZYRO

- a. Grip the TAKHZYRO prefilled syringe in one hand like a pencil (**Figure J**). Avoid touching the needle or pushing on the plunger rod.

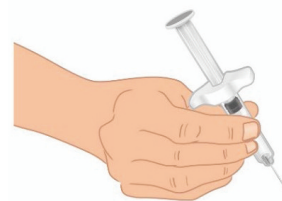


Figure J: Grip prefilled syringe

- b. With your other hand, gently pinch a 1-inch fold of skin at the cleaned injection site.
- Keep pinching until the injection is complete and the needle is removed (**Figure K**).

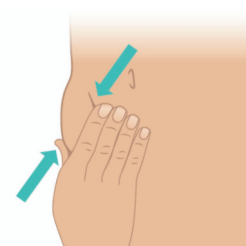


Figure K: Pinch a 1-inch fold of skin

- c. Using a quick dart-like motion, insert the needle at a 45-to-90-degree angle. Make sure to keep the needle in place (**Figure L**).

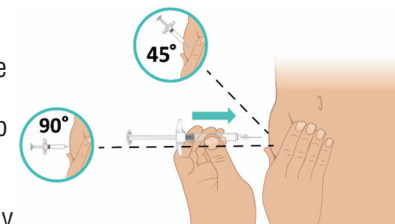


Figure L: Insert the needle

Important: Inject directly into the fatty layer under the skin (subcutaneous injection).

- d. Slowly push the plunger rod **all the way down until it stops** (**Figure M**).

Important: **Do not** remove the needle until all of the medicine is injected and the syringe barrel is empty. When the injection is complete, you will see the stopper at the bottom of the syringe barrel (**Figure N**).

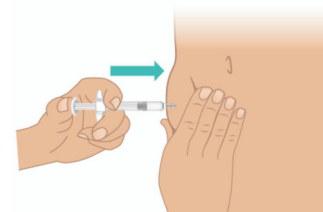


Figure M: Push the plunger rod all the way down

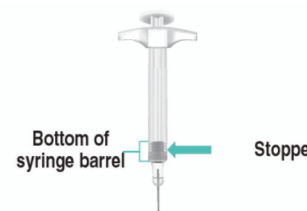


Figure N: Stopper at the bottom of the syringe barrel

- e. Slowly remove the needle while maintaining the syringe at the same angle. Gently release the fold of skin.

- f. Press a cotton ball or gauze pad over the injection site if needed and hold for 10 seconds.
- **Do not** rub the injection site. There may be a small amount of blood where you injected. This is normal.
 - Cover the injection site with an adhesive bandage if needed.

Step 4: Throw away (dispose of) TAKHZYRO prefilled syringe

- a. Put your used TAKHZYRO prefilled syringe in a sharps disposal container right away after use (**Figure 0**).



Figure 0: Dispose in a sharps container

- **Do not** recap the needle to avoid a needle-stick injury.
- **Do not** reuse the TAKHZYRO prefilled syringe or any of your injection supplies.
- **Do not** throw away (dispose of) the TAKHZYRO prefilled syringe in your household trash.
- **Do not** touch the needle.

FDA-cleared sharps containers are generally available through pharmacies, medical supply companies, healthcare providers, and online.

- If you do not have an FDA-cleared sharps container, you may use a household container that is:
 - made of a heavy-duty plastic
 - can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
 - upright and stable during use
 - leak-resistant, and
 - properly labeled to warn of hazardous waste inside the container.
- When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and syringes. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to FDA's website at: <http://www.fda.gov/safesharpsdisposal>.
- **Important:** Always keep the sharps disposal container out of the reach of children.
- **Do not** dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. **Do not** recycle your used sharps disposal container.

Questions?

For product or service-related questions, call 1-877-TAKEDA-7 (1-877-825-3327) or go to www.TAKHZYRO.com.

Manufactured by:

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