Before you use TAKHZYRO, tell your healthcare provider about all of your medical conditions, including if you:

- are pregnant or planning to become pregnant. It is not known if TAKHZYRO can harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if TAKHZYRO passes into your breastmilk. Talk to your healthcare provider about the best way to feed your baby while using TAKHZYRO.

Tell your healthcare provider about all the medicines you take, including prescription medicines, over-the-counter medicines, vitamins, or herbal supplements.

How should I use TAKHZYRO?

- See the detailed “Instructions for Use” that comes with this patient information leaflet about the right way to prepare and inject TAKHZYRO.
- Use TAKHZYRO exactly as your healthcare provider tells you to use it.
- TAKHZYRO is given as an injection under your skin (subcutaneous) by you or a caregiver.
- Your healthcare provider should show you or your caregiver how to prepare and inject your dose of TAKHZYRO before you inject yourself for the first time.
- Do not try to inject TAKHZYRO unless you have been trained by your healthcare provider.

What are the possible side effects of TAKHZYRO?

TAKHZYRO may cause serious side effects, including allergic reactions. Allergic reactions may happen with TAKHZYRO. Call your healthcare provider or get emergency help right away if you have any of the following symptoms:

- wheezing
- difficulty breathing
- chest tightness
- fast heartbeat
- faintness
- rash
- hives

The most common side effects of TAKHZYRO are:

- injection site reactions (pain, redness, and bruising)
- upper respiratory infections
- headache

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of TAKHZYRO. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

General information about the safe and effective use of TAKHZYRO.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use TAKHZYRO for a condition for which it is not prescribed. Do not give TAKHZYRO to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about TAKHZYRO that is written for health professionals.

What are the ingredients in TAKHZYRO?

Active ingredient: lanadelumab

Inactive ingredients: citric acid monohydrate, L-histidine, sodium chloride, sodium phosphate dibasic dihydrate and water for injection.

Manufactured by: Dyax Corp, 300 Shire Way, Lexington, MA 02421
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For more information, visit www.TAKHZYRO.com or call 1-800-828-2088.

This Patient Information has been approved by the U.S. Food and Drug Administration

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INSTRUCTIONS FOR USE
TAKHZYRO™ (tak-ZYE-roe)
(lanadelumab-flyo)
injection, for subcutaneous use

Be sure that you 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 solution for injection under the skin (subcutaneous). It is supplied in a single-dose, glass vial.
- Your healthcare provider will prescribe the dose that you should take.
- Only use the syringes, transfer needles, and injection needles that your healthcare provider prescribes.
- Only use the syringes, transfer needles and injection needles 1 time. Throw away (dispose of) any used syringes and needles.

Storing TAKHZYRO:
- Store TAKHZYRO in the refrigerator at 36°F to 46°F (2°C to 8°C). Do not freeze.
- Store TAKHZYRO in the original carton to protect the vial from light.
- Do not shake TAKHZYRO.
- Keep TAKHZYRO and all medicines out of the reach of children.

Supplies needed for your TAKHZYRO Injection

- 1 Vial containing TAKHZYRO
- TAKHZYRO Instructions for Use
- 2 Alcohol wipes
- 1 Empty 3 mL syringe
- 18G Transfer needle (longer needle)
  Do not use the transfer needle to inject TAKHZYRO.
- 27G ½-inch Injection needle (shorter needle)
  Do not use the injection needle to withdraw TAKHZYRO from the vial.
- Sharps disposal container. See “STEP 6” at the end of this Instructions for Use.

STEP 1: Prepare for your injection
- Gather all supplies and place them on a well-lighted flat work surface.
- Take the vial out of the refrigerator 15 minutes before use and allow it to reach room temperature before preparing an injection.
- Check the expiration date on the box and vial label of TAKHZYRO. Do not use if the expiration date has passed.
- Check the supplies for damage. Do not use if they appear damaged.
- Clean your work area and wash your hands before preparing your dose. Do not touch any surface or body part, especially your face, after washing your hands before injection.
- Remove the vial from the packaging. Do not use the vial if the plastic cap covering is missing.
  - Gently turn the vial upside down (invert) 3 to 5 times to mix the medicine. Do not shake to avoid foaming.
  - Look at the medicine in the vial for visible particles or a change in the color. Medicine should be colorless to slightly yellow. Do not use if you see particles or a change in color.
    Important: Do not shake.
  - Remove the plastic cap from the medicine vial. Do not remove the medicine vial rubber stopper.
STEP 2: Attach transfer needle to syringe

- Screw the 18G transfer needle to the 3mL syringe.
  
  **Important:** Do not remove the transfer needle cap from the needle when attaching to the syringe.

- Pull back the plunger to fill the syringe with air equal to the amount of medicine in the vial.

- Hold the syringe by the barrel with one hand and the transfer needle cap with the other hand.
  - Pull off the transfer needle cap straight away from the syringe and away from your body. **Do not** pull on the plunger. Place the transfer needle cap down on a clean flat surface.
  - **Do not touch** the needle tip.

STEP 3: Transfer TAKHZYRO into syringe and switch to the injection needle

- Keep the vial on the flat surface and insert the transfer needle into the center of the rubber stopper.
  - Push the plunger down to inject air into the vial and hold the plunger down.

- Slowly turn the vial upside down with transfer needle and syringe attached. Pull back on the plunger to **withdraw the full dose** in the vial.
  - **Important:** Be sure to keep the tip of the transfer needle in the medicine to avoid drawing air in as you pull back the plunger.

- Remove large air bubbles by gently tapping on the syringe barrel with your fingers until the bubbles rise to the top of the syringe.
  - Slowly push the plunger, allowing air to go back into the vial, until the medicine reaches the top of the syringe.
  - Repeat these steps until large air bubbles are removed.
  
  **Important:** Check again to make sure you have the right amount of medicine in your syringe. If you do not have enough medicine, pull back on the plunger again while keeping the needle in the medicine to get your **full dose**.

- Return the vial to an upright position.
  - Without removing the needle from the vial, unscrew the syringe by holding the needle hub and turning the syringe counter clockwise.
  - Return the syringe to an upright position.

- Throw away the 18G transfer needle and the vial in a sharps disposal container (See Step 6).

- Screw the 27G ½-inch injection needle to the syringe.
  
  **Important:** Do not remove the needle cap from the injection needle when attaching to the syringe. **Do not** use the transfer needle to inject TAKHZYRO as this may cause harm such as pain and bleeding.
**STEP 4: Select and prepare injection site**

- **TAKHZYRO** can be self-injected in your stomach (abdomen) or thigh. If given by a caregiver, **TAKHZYRO** may also be injected in the upper arm.
- Clean your injection site with an alcohol wipe and allow it to dry completely.

- **Important:**
  - You should use a different injection site each time you receive an injection to keep your skin healthy.
  - The area you choose for injection should be at least 2 inches (5 cm) away from any scars or your belly button (navel). **Do not** choose an area that is bruised, swollen, or painful.
  - **TAKHZYRO** should be given within 2 hours of preparing the dosing syringe at room temperature. After the dosing syringe is prepared, it can be refrigerated at 36°F to 46°F (2°C to 8°C) and must be used within 8 hours of preparation. Take the dosing syringe out of the refrigerator 15 minutes before use and allow it to reach room temperature prior to injecting.

**STEP 5: Inject TAKHZYRO**

- Hold the syringe by the barrel with one hand and the injection needle cap with the other hand.
- Pull off the injection needle cap straight away from the syringe and away from your body. **Do not** pull on the plunger. **Do not** touch the needle tip or allow it to touch any other surface.
- Gently pinch about 1 inch of skin at your cleaned chosen injection site and insert the needle. **Important:** Be sure to inject under the skin which is not too shallow (skin layer) or too deep (muscle).
- Push the plunger slowly until no medicine remains in the syringe. Release the skin fold and gently remove the needle. **Do not** recap the needle.

**STEP 6: THROW AWAY (DISPOSE OF) NEEDLE AND SYRINGE**

- Place the 27G ½-inch Injection needle and the syringe in a sharps container.
- **Important:** Always keep the sharps disposal container out of the reach of children.
- If you do not have a FDA-cleared sharps disposal, you may use a household container that is:
  - Made of 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 in the state you live in, go to the FDA's website at: http://www.fda.gov/safesharpsdisposal.

For more information, visit www.TAKHZYRO.com

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Manufactured by:

Dyax Corp.

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