

TAKHZYRO SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE 150MG/ML

Lanadelumab 150mg/1mL, 300mg/2mL

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What TAKHZYRO is used for

TAKHZYRO is used in patients aged 2 and older to prevent angioedema attacks in patients with hereditary angioedema (HAE).

How TAKHZYRO works

TAKHZYRO is a type of protein that blocks the activity of plasma kallikrein. This helps to reduce the amount of bradykinin in the bloodstream and prevents symptoms of HAE.

Before you use TAKHZYRO

- When you must not use it

Do not take this medicine if:

- you are allergic to lanadelumab or any other ingredients of this medicine (listed in Product Description)

- Before you start to use it

Check with your doctor or pharmacist if you:

- are using TAKHZYRO before you have laboratory tests to measure how well your blood is clotting. TAKHZYRO in the blood may interfere with some laboratory tests, leading to inaccurate results.
- Take any medicines for any other condition

Pregnancy and lactation

Please consult your doctor or pharmacist if you are pregnant, planning

for pregnancy or breast-feeding before using any medicine.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

How to use TAKHZYRO

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- How much to use

Adult patients: the recommended starting dose is 300 mg every 2 weeks. If you have not had an attack for a long period, your doctor may change the dose to 300 mg every 4 weeks.

12 to <18 years patients: the recommended dose is 300 mg every 2 weeks. If you have not had an attack for a long period, your doctor may change the dose to 300 mg every 4 weeks

6 to <12 years patients: the recommended dose is 150 mg every 2 weeks. If you have not had an attack for a long period, your doctor may change the dose to 150 mg every 4 weeks

2 to <6 years patients: the recommended dose is 150 mg every 4 weeks.

See section on instructions for use for the dose to inject

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Use this medicine for the duration that your doctor recommends.

- If you forget to use it

Take the missed dose as soon as you remember but there must be at least 10 days between each dose for adult and 6 to <12 years patients, and at least 24 days for patients aged 2 to <6 years.

Do not inject a double dose to make up for the dose that you missed.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you or anyone else may have use too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using TAKHZYRO

- Things you must do

Use your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are using TAKHZYRO.

Tell your doctor immediately if you become pregnant while using this medication.

Take TAKHZYRO only with a doctor's prescription.

- Things you must not do

Do not stop using the medicine unless advised by your doctor.

Do not use any new medicines without consulting your doctor or pharmacist.

Do not give TAKHZYRO to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

This medicine has no or negligible influence on the ability to drive and use machines.

Side effects

Like all medicines, TAKHZYRO can cause side effects, although not everybody gets them.

Very common (may affect more than 1 in 10 people):

- Reactions where the injection is given – symptoms include pain, skin redness, bruising, discomfort, swelling, bleeding, itching, hardening of skin, tingling, warmth and rash.

Common (may affect up to 1 in 10 people):

- Allergic reactions including itching, discomfort and tingling of the tongue
- Dizziness, feeling faint
- Raised skin rash
- Muscle pain
- Blood tests showing liver changes

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of TAKHZYRO

- Storage

Keep out of the reach and sight of children.

Store in a refrigerator at 2°C to 8°C. Do not freeze. Keep the pre-filled syringe in the outer carton in order to protect from light.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

TAKHZYRO is presented as a clear, colourless to slightly yellow solution for injection in a pre-filled syringe.

Each TAKHZYRO pre-filled syringe contains either 300 mg of lanadelumab in 2 mL solution or 150 mg of lanadelumab in 1 mL solution.

- Ingredients

- Active ingredient(s)

- Lanadelumab 150mg/mL
- Lanadelumab 300mg/2mL

- Inactive ingredients

- Sodium phosphate dibasic, dihydrate
- Citric acid monohydrate
- L-histidine
- Sodium chloride
- Polysorbate 80
- Water for injection

- MAL number(s):

MAL*****
MAL*****

Manufacturer

DP Manufacturer:

Vetter Pharma-Fertigung GmbH & Co.
KG
Schuetzenstrasse 87 and 99-101
88212 Ravensburg
Germany

Batch releaser:

Takeda Pharmaceuticals International AG
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Block 2 Miesian Plaza,
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Dublin 2, D02 HW68
Ireland

Product Registration Holder

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Unit TB-L 13-1, Level 13,
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Malaysia

Date of revision

08/05/2026

Serial Number

NPRA (R3)26/106

INSTRUCTION FOR USE

TAKHZYRO is for injection under the skin (subcutaneous injection). Do not inject it into a vein or muscle.

Parts of your TAKHZYRO pre-filled syringe before use (Figure A).

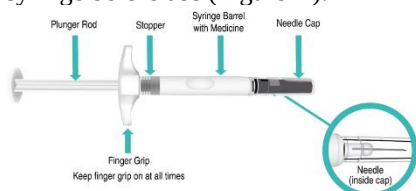


Figure A: TAKHZYRO pre-filled syringe

STEP 1: Prepare for your injection

a. 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.

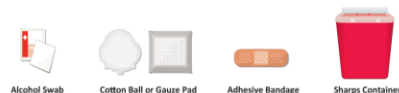


Figure B: Supplies

b. Remove TAKHZYRO pre-filled syringe from refrigerator.

- Do not use the TAKHZYRO pre-filled syringe if the tamper evident seal is open or broken.
- Before you prepare your injection, allow the pre-filled syringe to reach room temperature for at least 15 minutes.
- Your medicine is sensitive to warm temperatures. Do not use heat sources such as a microwave or hot water to warm your TAKHZYRO pre-filled syringe.
- Do not remove the needle cap until you are ready to inject.



c. Open the carton. Hold the syringe barrel and remove the TAKHZYRO pre-filled syringe from the tray (Figure C).

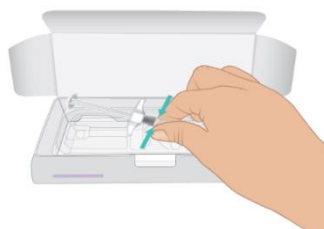


Figure C: Remove pre-filled syringe

d. 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

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



Figure E: Location of expiration date

f. Inspect the TAKHZYRO pre-filled syringe for any damage and make sure the medicine is colourless to slightly yellow (Figure F).

- Do not use product if syringe is damaged – e.g., cracked syringe.
- Do not use the TAKHZYRO pre-filled syringe if the medicine is discoloured, cloudy or has flakes or particles in it.

- You might see air bubbles in the TAKHZYRO pre-filled syringe. This is normal and will not affect your dose.

If you cannot use the pre-filled syringe, contact your healthcare provider.

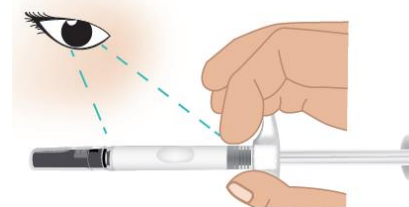


Figure F: Inspect the pre-filled syringe

STEP 2: Select and prepare your injection site

a. The TAKHZYRO pre-filled syringe should be injected into the following sites only (Figure G):

- o stomach area (abdomen)
- o thighs
- o upper arms (only if healthcare provider or caregiver is giving you the injection)

- Do not inject into an area of your body where the skin is irritated, reddened, bruised, or infected.

- The area you choose for injection should be at least 5 cm away from any scars or your belly button (navel).

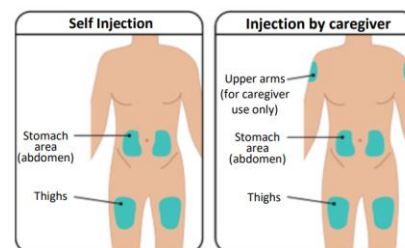


Figure G: Injection sites

Important: Rotate injection sites to keep skin healthy. Each new injection should be given at least 3 cm 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 this area again before giving your injection.



Figure H: Clean injection site

c. Firmly hold the middle of the TAKHZYRO pre-filled syringe with one hand and with the other hand, gently pull the needle cap straight off. Throw away the needle cap in your trash or in your sharps container (Figure I).

- Do not touch or push the plunger rod until you are ready to inject.
- Do not recap your TAKHZYRO pre-filled syringe to avoid a needle stick injury.
- Do not use the TAKHZYRO pre-filled syringe if it has been dropped without the needle cap.
- Do not use the TAKHZYRO pre-filled syringe if the needle looks damaged or bent.
- Do not touch the needle or allow the needle to touch anything.

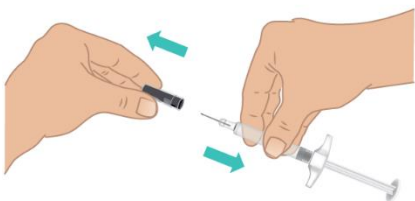


Figure I: Remove needle cap

STEP 3: Inject TAKHZYRO

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



Figure J: Grip pre-filled syringe

b. With your other hand, gently pinch about 3 cm fold of skin at the cleaned injection site.

- Keep pinching until the injection is complete and the needle is removed (Figure K)

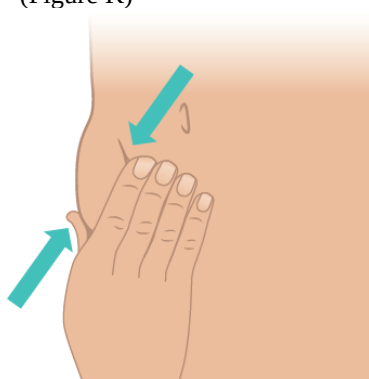


Figure K: Pinch 3cm fold of skin

c. With one quick, short motion, push needle all the way into skin at a 45-to-90 degree angle. Make sure to keep the needle in place (Figure L).

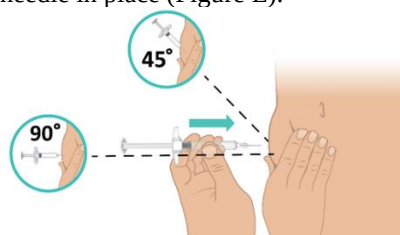


Figure L: Insert the needle

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).

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



Figure M: Push the plunger rod all the way down

Important: Do not withdraw 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).

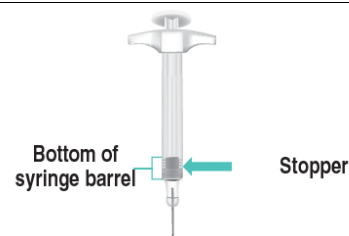


Figure N: Stopper at the bottom of the syringe barrel

f. Press cotton ball or gauze pad over injection site if needed and hold for 10 seconds.

- Do not rub the injection site. You may have a minor bleeding. This is normal.
- Cover injection site with an adhesive bandage if needed.

g. Throw away (dispose) your used TAKHZYRO pre-filled syringe.

- Put your used TAKHZYRO pre-filled syringe in a sharps disposal container right away after use (Figure O).
- Do not recap the needle to avoid needle stick injury.
- Do not reuse the TAKHZYRO pre-filled syringe and any of your injection supplies.
- Do not touch the needle.

Important: Always keep the sharps disposal container out of the reach of children.



Figure O: Dispose in a sharps container

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