

Package leaflet: Information for the user

TAKHZYRO 300 mg solution for injection in pre-filled syringe

lanadelumab

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What TAKHZYRO is and what it is used for
2. What you need to know before you use TAKHZYRO
3. How to use TAKHZYRO
4. Possible side effects
5. How to store TAKHZYRO
6. Contents of the pack and other information
7. Instructions for use

1. What TAKHZYRO is and what it is used for

TAKHZYRO contains the active substance lanadelumab.

What TAKHZYRO is used for

TAKHZYRO is a medicine used in patients 2 years and older to prevent angioedema attacks, in patients with hereditary angioedema (HAE).

What hereditary angioedema (HAE) is

HAE is a condition which runs in families. With this condition your blood does not have enough of a protein called 'C1 inhibitor', or C1 inhibitor does not work properly. This leads to too much 'plasma kallikrein', which in turn produces higher levels of 'bradykinin' in your bloodstream. Too much bradykinin leads to symptoms of HAE like swelling and pain on the,

- hands and feet
- face, eyelids, lips or tongue
- voice-box (larynx), which may make breathing difficult
- genitals

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 your bloodstream and prevents symptoms of HAE.

2. What you need to know before you use TAKHZYRO

Do not use TAKHZYRO

If you are allergic to lanadelumab or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

- Talk to your doctor, pharmacist or nurse before using TAKHZYRO.
- If you have a severe allergic reaction to TAKHZYRO with symptoms such as a rash, a tight chest, wheezing, or a fast heartbeat, tell your doctor, pharmacist or nurse **immediately**.

Keeping a record

It is strongly recommended that every time you have a dose of TAKHZYRO, you write down the name and batch number of the medicine. This is so that you keep a record of the batches used.

Laboratory tests

Tell your doctor if you are using TAKHZYRO before you have laboratory tests to measure how well your blood is clotting. This is because TAKHZYRO in the blood may interfere with some laboratory tests, leading to inaccurate results

Children and adolescents

TAKHZYRO is not recommended for use in children under 2 years of age. This is because it has not been studied in this age group.

Other medicines and TAKHZYRO

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

TAKHZYRO is not known to affect other medicines or be affected by other medicines.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before starting to use TAKHZYRO. There is limited information on the safety of TAKHZYRO use during pregnancy and breast-feeding. As a precautionary measure, it is preferable to avoid the use of lanadelumab during pregnancy and breast-feeding. Your doctor will discuss with you the risks and benefits of taking this medicine.

Driving and using machines

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

TAKHZYRO contains sodium

The medicine contains less than 1 mmol sodium (23 mg) per pre-filled syringe, that is to say essentially 'sodium-free'.

3. How to use TAKHZYRO

TAKHZYRO is provided in single-use pre-filled syringes as ready-to-use solution. Your treatment will be started and managed under the supervision of a doctor experienced in the care of patients with HAE.

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure or have any further questions on the use of this medicine.

How much TAKHZYRO to use

For adults and adolescents 12 to less than 18 years of age:

- The recommended starting dose is 300 mg lanadelumab every 2 weeks. If you have not had an attack for a long period, your doctor may change the dose to 300 mg lanadelumab every 4 weeks, especially if you have a low body weight.
- In patients with a body weight less than 40 kg, a starting dose of 150 mg lanadelumab every 2 weeks may also be considered. If you have not had an attack for a long period, your doctor may change the dose to 150 mg lanadelumab every 4 weeks.

For children 2 to less than 12 years of age, the recommended dose is based on body weight:

Body Weight (kg)	Recommended Starting Dose	Dose Adjustment
10 to less than 20 kg	150-mg lanadelumab every 4 weeks	A dose increase to 150 mg lanadelumab every 3 weeks may be considered in patients with insufficient control of attacks
20 to less than 40 kg	150-mg lanadelumab every 2 weeks	A dose reduction to 150 mg lanadelumab every 4 weeks may be considered in patients who are stably attack free on treatment
40 kg or more	300-mg lanadelumab every 2 weeks	A dose reduction to 300 mg lanadelumab every 4 weeks may be considered in patients who are stably attack free on treatment

- For patients with a body weight of 20 to less than 40 kg who have not had an attack for a long period, the doctor may allow your child or the child you are caring for to continue with the same dose when reaching 12 years of age.

How to inject TAKHZYRO

If you inject TAKHZYRO yourself or if your caregiver injects it, you or your caregiver must carefully read and follow the instructions in section 7, “Instructions for use”.

- TAKHZYRO is for injection under the skin (‘subcutaneous injection’).
- The injection can be given either by yourself or a caregiver for patients 12 years and over.
- The injection can be given by either healthcare provider or caregiver for patients 2 to less than 12 years of age. A doctor, pharmacist or nurse should show you how to prepare and inject TAKHZYRO properly before you use it for the first time. Do not inject yourself or someone else until you have been trained to inject the medicine.
- Insert the needle into the fatty tissue in the tummy (abdomen), thigh or upper arm.
- Inject the medicine in a different place each time.

- Use each pre-filled syringe of TAKHZYRO only once.

If you use more TAKHZYRO than you should

Tell your doctor, pharmacist or nurse if you take too much TAKHZYRO.

If you forget to use TAKHZYRO

If you miss a dose of TAKHZYRO, inject your dose as soon as possible. The next dose scheduled may need to be adjusted based on the intended dosing frequency to ensure

- at least 10 days between doses for patients on every 2 weeks dosing schedule,
- at least 17 days between doses for patients on every 3 weeks dosing schedule,
- at least 24 days between doses for patients on every 4 weeks dosing schedule.

If you are not sure when to inject TAKHZYRO after a missed dose, ask your doctor, pharmacist or nurse.

If you stop using TAKHZYRO

It is important that you keep injecting TAKHZYRO as instructed by your doctor even if you feel better. If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

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

If you have a severe allergic reaction to TAKHZYRO with symptoms such as a rash, tight chest, wheezing, or a fast heart beat, tell your doctor, pharmacist or nurse **immediately**.

Tell your doctor, pharmacist or nurse if you notice any of the following side effects.

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

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store TAKHZYRO

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

TAKHZYRO 300 mg solution for injection in pre-filled syringe

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

Pre-filled syringes may be stored below 25°C for a single period of 14 days, but not beyond the expiry date.

Do not return TAKHZYRO to refrigerated storage after storage at room temperature.

When one pre-filled syringe from a multi-pack is removed from refrigeration, return the remaining pre-filled syringes to the refrigerator until future use when needed.

Do not use this medicine if you notice signs of deterioration such as particles in the pre-filled syringe or changed colour of the injection solution.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What TAKHZYRO contains

- The active substance is lanadelumab. Each pre-filled syringe contains 300 mg of lanadelumab in 2mL solution.
- The other ingredients are disodium phosphate dihydrate, citric acid monohydrate, histidine, sodium chloride, polysorbate 80 and water for injections – see section 2 “TAKHZYRO contains sodium”

What TAKHZYRO looks like and contents of the pack

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

TAKHZYRO is available as:

- a single pack containing one 2 ml pre-filled syringe in a carton
- a single pack containing two 2 ml pre-filled syringes in a carton
- in multipacks comprising 3 cartons, each carton containing two 2 ml pre-filled syringes.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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Manufacturer

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7 Instructions for use

Be sure that you read, understand, and follow the Instructions for Use before injecting TAKHZYRO. Contact your healthcare provider if you have any questions.

Intended use

The TAKHZYRO pre-filled syringe is a fixed dose (300 mg/2 mL), ready-to-use, disposable, needle-based injection device intended for subcutaneous administration of the drug product by healthcare providers, caregivers, or by self-administration (for patients 12 years and older)

Storing TAKHZYRO

- Store the TAKHZYRO pre-filled syringe in the refrigerator at 2°C to 8°C. **Do not** freeze.
- Pre-filled syringe removed from refrigeration should be stored below 25°C and used within 14 days. Do not return TAKHZYRO to refrigerated storage after storage at room temperature.
- When one pre-filled syringe from a multi-pack is removed from refrigeration, return the remaining pre-filled syringes to the refrigerator until future use when needed.
- Store TAKHZYRO in the original carton to protect the pre-filled syringe from light.
- Throw away (discard) the TAKHZYRO pre-filled syringe if it has been kept out of the refrigerator, frozen, or not kept in the original carton protected from light.
- **Do not** shake TAKHZYRO.
- **Keep TAKHZYRO and all medicines out of the reach of children.**

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

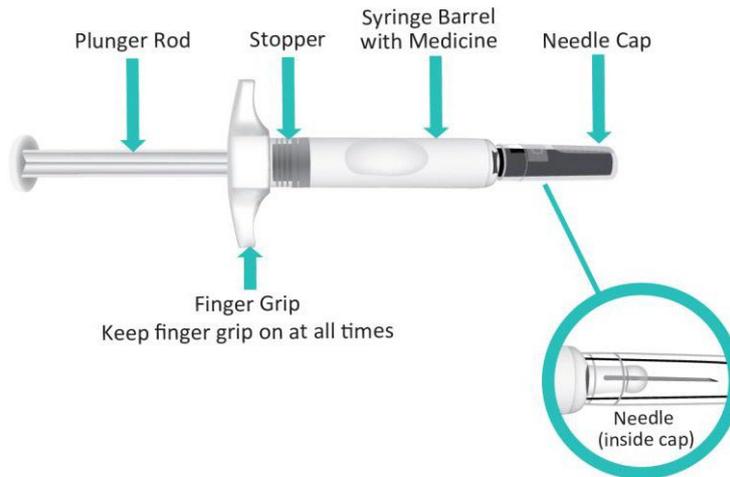


Figure A: TAKHZYRO pre-filled syringe

STEP 1: Prepare for your injection

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

Figure B



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**).

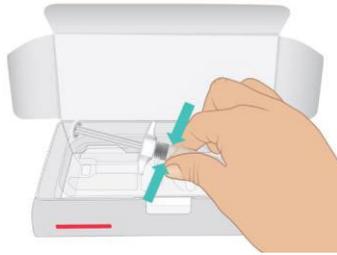


Figure C: Remove pre-filled syringe

d. Wash your hands with soap and water (Figure D). Dry your hands completely Check the expiration date on the label (Figure D).

- **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.

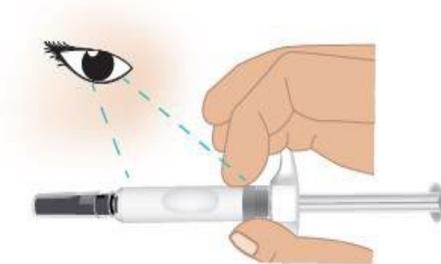


Figure F: Inspect the pre-filled syringe

STEP 2: Select and prepare your injection site

a. The TAKHZYRO pre-filled syringe should be injected into the following sites only

(Figure G):

- stomach area (abdomen)
- thighs
- 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).

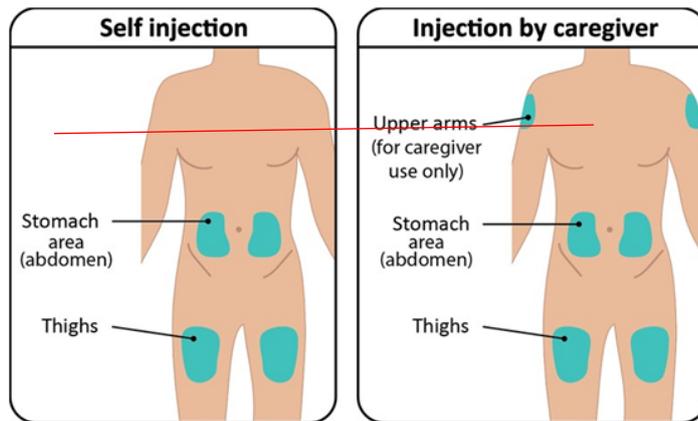


Figure G: Injection sites

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.

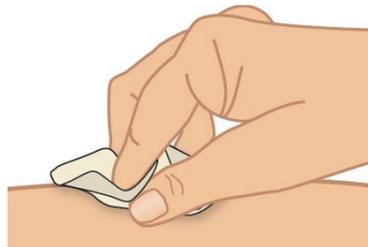


Figure H: Clean injection site

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

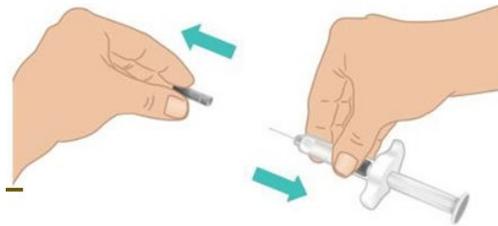


Figure I: Remove the needle cap

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**).

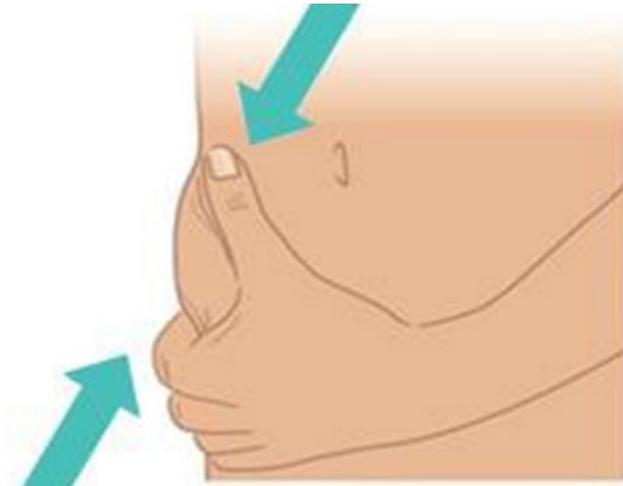


Figure K: Pinch 3 cm fold of skin

- 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**).

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



Figure L: Insert the needle

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



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).

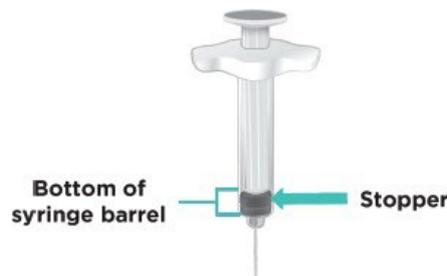


Figure N: Stopper at the bottom of the syringe barrel

- e. Slowly withdraw needle while maintaining the syringe at the same angle. Gently release fold of skin.).
- 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
 - Put your used TAKHZYRO pre-filled syringes in a sharps disposal container right away after use.
 - **Do not** touch the needle



Figure O: Dispose in a sharps container

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