

Package leaflet: Information for the user

TAKHZYRO 300 mg solution for injection in pre-filled pen

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 pen, that is to say essentially 'sodium-free'.

3. How to use TAKHZYRO

TAKHZYRO is provided in single-use pre-filled pens 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. However, the 150 mg pre-filled syringe must be used because the 300 mg pre-filled pen cannot be used to administer 150 mg lanadelumab.

For children 2 to less than 12 years of age:

- The recommended dose is based on body weight and should only be administered via a pre-filled syringe or vial. The pre-filled pen has not been studied in children 2 to less than 12 years of age and therefore should not be used.

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 older.
- 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.
- Administer TAKHZYRO with the pre-filled pen 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 pen 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 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 and on the carton after EXP. . The expiry date refers to the last day of that month.

TAKHZYRO 300 mg solution for injection in pre-filled pen

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

Pre-filled pens 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 pen from a multi-pack is removed from refrigeration, return the remaining pre-filled pens 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 pen 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 pen 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 pen.

TAKHZYRO is available as:

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

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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Manufacturer

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Dublin 2
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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 pen 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 the TAKHZYRO pre-filled pen

- Store the TAKHZYRO pre-filled pen in the refrigerator at 2 °C to 8 °C. **Do not** freeze.
- Store TAKHZYRO in the original carton to protect the pre-filled pen from light.
- Pre-filled pens removed from refrigeration should be stored below 25 °C and used within 14 days. Do not return TAKHZYRO to refrigerated storage after leaving the pen out at room temperature.
- After removing one pre-filled pen from a multi-pack, return the remaining pre-filled pens to the refrigerator in the original carton until future use when needed.
- Throw away (dispose of) the TAKHZYRO pre-filled pen if it has been kept out of the refrigerator for more than 14 days, 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.**

The TAKHZYRO pre-filled pen (**Figure A**) is for single use only.

TAKHZYRO pre-filled pen before and after use

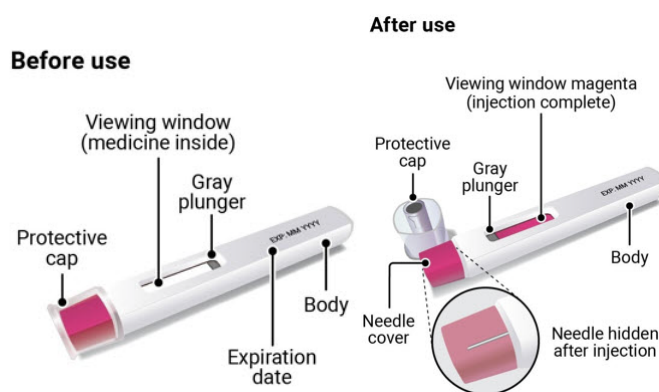


Figure A

Prepare for your injection

Step 1 - Prepare your pre-filled pen

Remove the TAKHZYRO pre-filled pen carton from the refrigerator 30 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 pre-filled pen.



Step 2 - Gather supplies

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 pre-filled pen carton.



Figure B

Step 3 - Remove pre-filled pen

Open the carton. Hold the pen body and remove the TAKHZYRO pre-filled pen from the tray (**Figure C**).

- **Do not** remove the protective cap until you are ready to inject.
- **Do not** touch or push the needle cover until you are ready to inject.



Figure C

Step 4 – Wash hands

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

Step 5 – Check expiration date

Check the expiration date (EXP) on the pen body (Figure E).

- **Do not** use the TAKHZYRO pre-filled pen if the expiration date has passed. If the TAKHZYRO pre-filled pen is expired throw it away (dispose of) in a sharps disposal container and contact your healthcare provider.

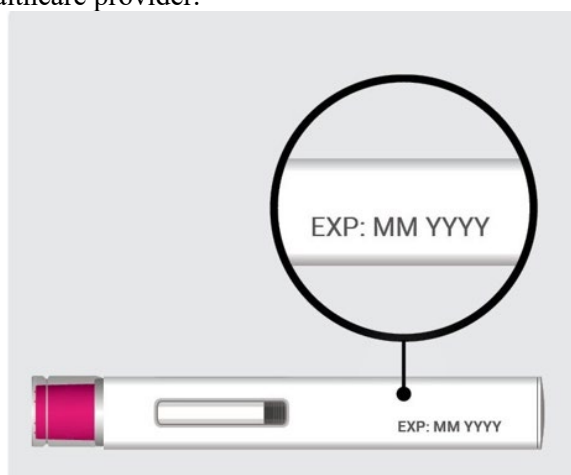


Figure E

Step 6 – Inspect TAKHZYRO

Inspect the TAKHZYRO pre-filled pen for any damage. Check the viewing window (**Figure F**) and make sure the medicine is colourless to slightly yellow.

- **Do not** use the TAKHZYRO pre-filled pen if the pen is damaged or cracked.
- **Do not** use the TAKHZYRO pre-filled pen if the medicine is discoloured, cloudy, or has flakes or particles in it.
- You may see air bubbles in the TAKHZYRO pre-filled pen viewing window. This is normal and will not affect your dose.

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

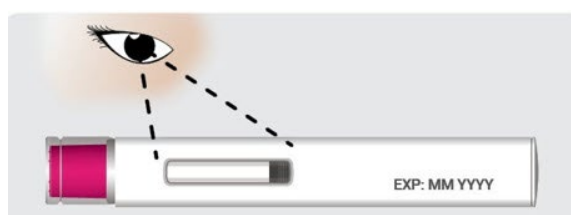


Figure F

Select and prepare your injection site

Step 7 – Select your injection site

TAKHZYRO should be injected into the following sites only (**Figure G for self-injection and Figure H for caregiver injection**):

- stomach area (abdomen)
- thighs
- upper arms (only if a healthcare provider or caregiver is giving you the injection)
- **Do not** inject into an area of your body where the skin is irritated, red, bruised, or infected.
- The area you choose for injection should be at least 5 cm away from any scars or your belly button (navel).

Important:

Rotate injection sites to keep skin healthy. Each new injection should be given at least 2.5 cm from the last site you used.

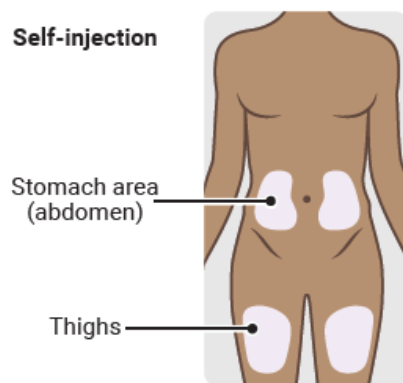


Figure G

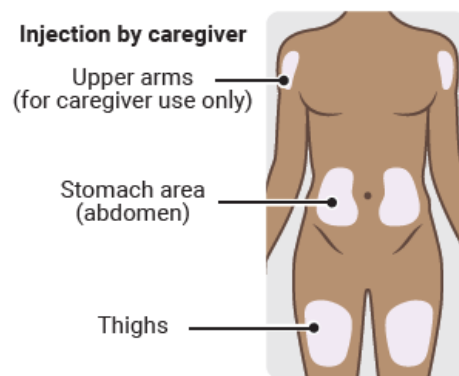


Figure H

Step 8 - Clean injection site

Clean the injection site with an alcohol swab and allow it to dry completely (**Figure I**).

- **Do not** fan or blow on the clean site.
- **Do not** touch the clean site again before giving your injection.



Figure I

Step 9 - Remove protective cap

Firmly hold the middle of the TAKHZYRO pre-filled pen with one hand, and with the other hand, pull the protective cap straight off (**Figure J**).

- The needle is protected by the needle cover.
- You may see a few drops of liquid come out of the needle. This is normal and will not affect your dose of TAKHZYRO.
- Your TAKHZYRO pre-filled pen is ready to inject after the protective cap is removed.

- **Do not** touch or push the needle cover until you are ready to inject.
- **Do not** recap your TAKHZYRO pre-filled pen.

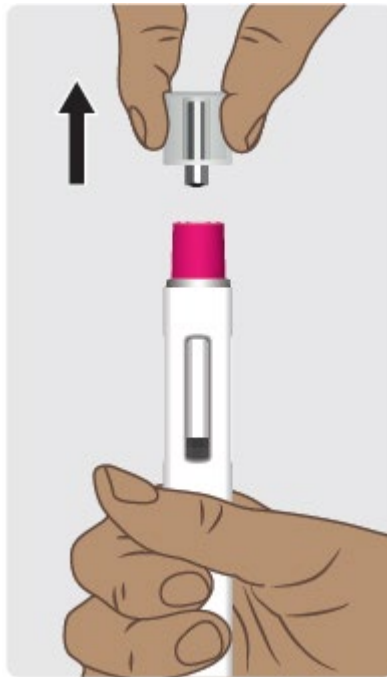


Figure J

Step 10 – Dispose of protective cap

Throw away (dispose of) the protective cap in your trash or in your sharps disposal container (**Figure K**).

- **Do not** recap the pen to avoid a needlestick injury.



Figure K

Inject TAKHZYRO

Step 11 – Hold the TAKHZYRO pre-filled pen and pinch the skin

Hold the TAKHZYRO pre-filled pen in one hand so that you can see the viewing window while giving the injection (**Figure L**).

With your other hand, gently pinch a 2.5 cm fold of skin at the cleaned injection site (**Figure M**).

- Keep pinching until the injection is complete and the needle is removed.
- **Do not** press the needle cover against your skin until you are ready to give the injection.



Figure L



Figure M

Step 12 - Place pen on injection site

Place your TAKHZYRO pre-filled pen on your skin at a 90-degree angle to the chosen injection site (**Figure N**).

- **Do not** push down on the pen until you are ready to inject.
- Hold your pen so you can see the viewing window.

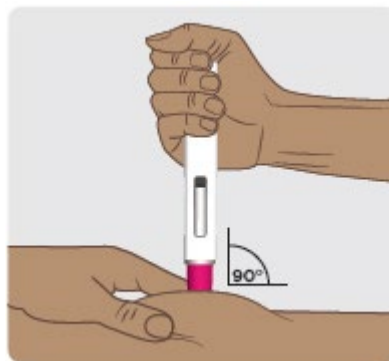


Figure N

Step 13 - Inject TAKHZYRO

Firmly press your pen straight down and hold. This will insert the needle and start your injection (**Figure O**).

Your injection may take up to 25 seconds.

- You will hear a “click” sound when the injection starts.
- There will be a second “click” – **this is not the end of the injection.**
- Continue to hold down with constant pressure, until the **viewing window is completely filled with the colour magenta.**
- **Before you remove the pen from your skin, confirm that the viewing window is filled with magenta.** This means you have received your full dose (**Figure O**).
- The grey plunger is still visible in the viewing window after the injection is complete. This is normal and will not affect your dose.
- If the viewing window did not fill completely with magenta, contact your healthcare provider.

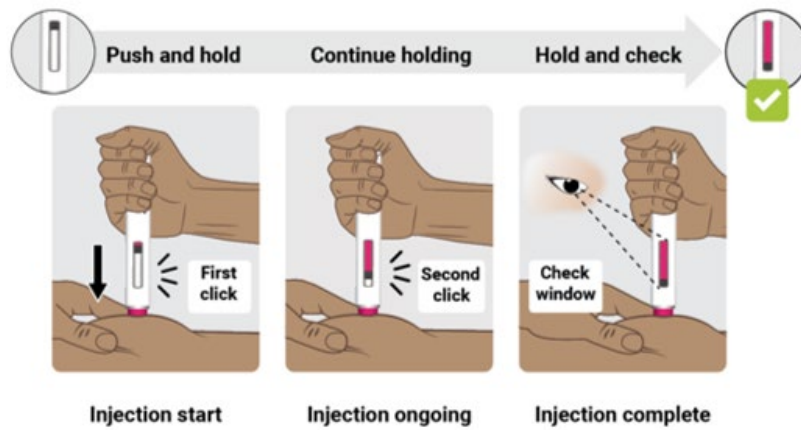


Figure O

Step 14 - Remove pen

Slowly lift your pen straight away from the injection site. The needle cover will be covering all of the needle (**Figure P**).

- Release the fold of skin.
- **Do not rub** the injection site. There may be a small amount of blood where you injected. This is normal.
- Press a cotton ball or gauze pad over the injection site and cover with an adhesive bandage, if needed.

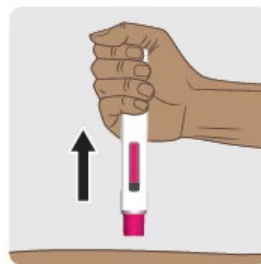


Figure P

Throw away (dispose of) the TAKHZYRO pre-filled pen

Step 15 – Dispose in a sharps disposal container

Put your used TAKHZYRO pre-filled pen in a sharps disposal container right away after use (**Figure Q**).

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

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



Figure Q

