

Package leaflet: Information for the user

TAKHZYRO 300 mg solution for injection in vial

lanadelumab

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

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 adults, and adolescents aged 12 years and older to prevent angioedema attacks, in patients with 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 12 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 Takhzryo. 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 negligible influence on the ability to drive or use machines.

TAKHZYRO contains sodium

The medicine contains less than 1 mmol sodium (23 mg) per ml of solution, that is to say essentially 'sodium-free'.

3. How to use TAKHZYRO

TAKHZYRO is provided in single-use vials 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

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, especially if you have a low body weight.

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.
- 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 vial 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 but there must be at least 10 days between each dose. 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.

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

Vials 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.

Do not use this medicine if you notice signs of deterioration such as particles in the vial 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 vial 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 glass vial.

TAKHZYRO is available as a single pack containing one 2 ml vial and in multipacks comprising 2 or 6 cartons, each carton containing 1 vial.

Not all pack sizes may be marketed.

Each pack also contains the following items:

- Empty 3 ml syringe
- 18 gauge blunt tip vial access needle
- 27 gauge x 13 mm pointed tip administration (injection) needle.

Marketing Authorisation Holder and Manufacturer

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Tel: +80066838470

E-mail: medinfoEMEA@shire.com

This leaflet was last revised in 05/2020.

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site: <https://www.ema.europa.eu/> There are also links to other websites about rare diseases and treatments.

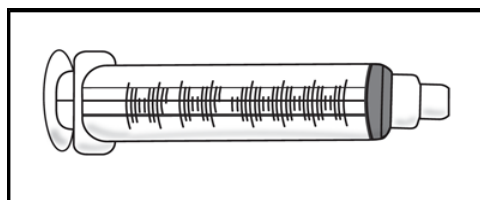
This leaflet is available in all EU/EEA languages on the European Medicines Agency website.

7. Instructions for use

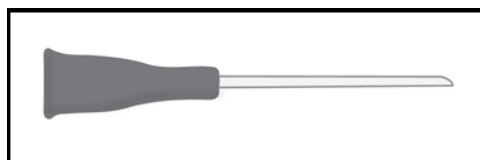
Be sure that you read, understand and follow the step-by-step instructions for injecting TAKHZYRO. Contact your doctor, pharmacist or nurse if you have any questions.

In addition to the vial, each TAKHZYRO pack also contains:

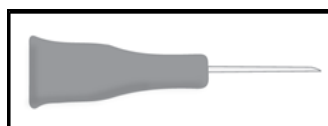
- One empty 3 ml syringe.



- One 18 gauge blunt tip vial access needle.
Used to draw medicinal solution from the vial into the syringe.



- One 27 gauge x 13 mm pointed tip injection needle.
Used for injection under the skin (subcutaneous).



Only use the syringes, blunt-tip vial access needles and pointed-tip injection needles in this pack or which your doctor has prescribed.

Only use the syringes, blunt-tip vial access needles and pointed-tip injection needles one time. Place all used syringes and needles in the sharps container.

Do not use any syringes, blunt-tip vial access needles and pointed-tip injection needles that appear damaged.

You will also need:

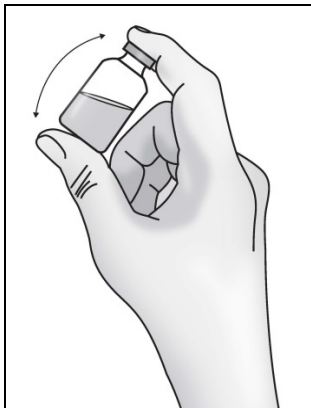
- Alcohol wipes
- A sharps container for used vials, needles and syringes

You can get supplies from your doctor, pharmacist or nurse.

The injection of TAKHZYRO can be summarised in 5 steps:

- 1. Prepare the vial of TAKHZYRO**
- 2. Attach blunt tip vial access needle to syringe**
- 3. Transfer TAKHZYRO into syringe and switch to the pointed-tip injection needle**
- 4. Select and prepare injection site**
- 5. Inject TAKHZYRO**

Step 1: Prepare the vial of TAKHZYRO

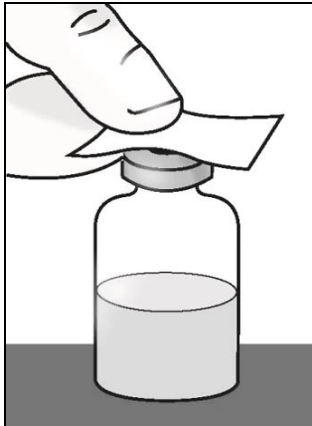


- a) Take the vial out of the refrigerator 15 minutes before use to allow it to reach room temperature (15°C to 25°C) before preparing an injection.
- b) Clean your work area and wash your hands before preparing your dose. Do not touch any surface or your body, especially your face, after washing your hands before injection.
- c) Gather your TAKHZYRO and supplies and place them on your well-lit work surface.
- d) Remove the vial from the packaging. Do not use the vial if the cap covering the stopper is missing.
- e) **Gently invert the vial 3 to 5 times to ensure the solution is mixed. Do not shake the vial as this can cause foaming.**
- f) Check the solution in the vial for particles or a change in the colour (normally it is colourless to slightly yellow). Do not use if you see particles or a change in colour.

Important: Do not shake.

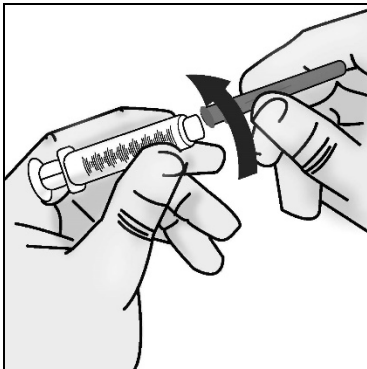


- g) Remove the plastic cap from the vial. Do not remove the vial rubber stopper.



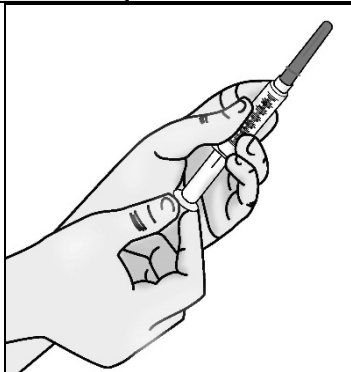
- h) Place the vial on a flat surface. Clean the vial rubber stopper with an alcohol wipe and allow it to dry.

Step 2: Attach blunt tip vial access needle to syringe

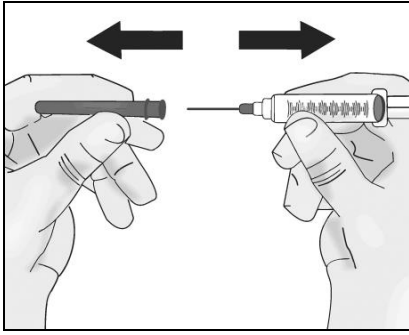


- a) Screw the 18 gauge blunt tip vial access needle to the 3 ml syringe.

Important: Do not remove the needle cap from the needle when attaching to the syringe.

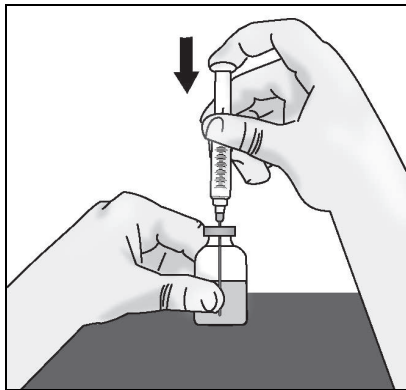


- b) Pull back the plunger to fill the syringe with air equal to the amount of solution in the vial.

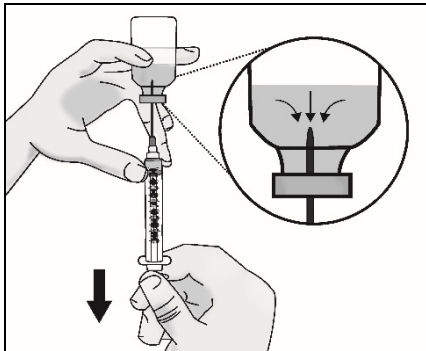


- c) Pull off the needle cap straight away from the syringe without touching the needle. Do not pull on the plunger.

Step 3: Transfer TAKHZYRO into syringe and switch to the pointed-tip injection needle

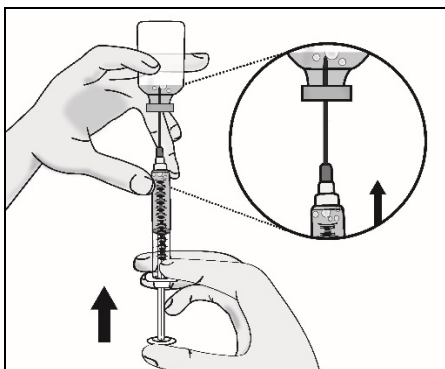


- a) Insert the needle into the centre of the rubber stopper.
- b) Push the plunger down to inject air into the vial and hold the plunger down.



- c) Slowly turn the vial upside down with needle and syringe attached. Pull back on the plunger to **withdraw the full dose** in the vial.

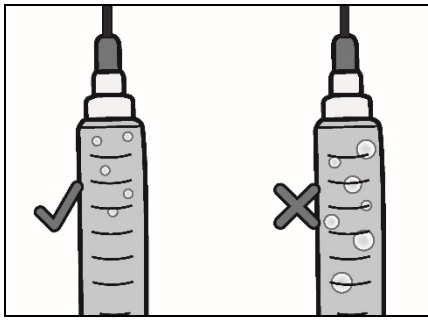
Important: Be sure to keep the tip of the needle in the liquid to avoid drawing air in as you pull back the plunger.



- d) Remove large air bubbles by gently tapping on the syringe with your fingers until the bubbles rise to the top of the syringe.

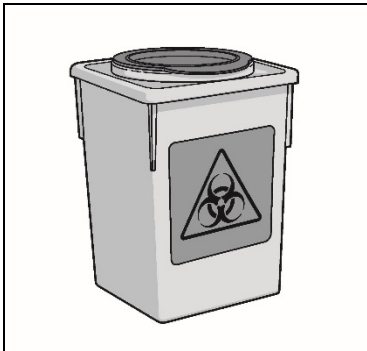
Slowly push the plunger, allowing air to go back into the vial, until the solution reaches the top of the syringe.

Repeat these steps until large air bubbles are removed.

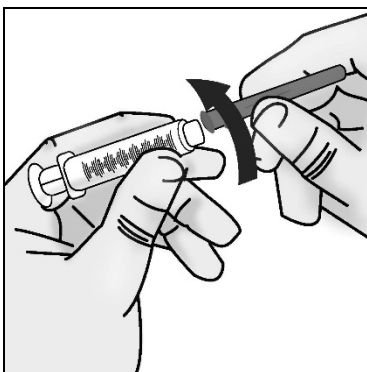


- e) Without removing the needle from the vial, unscrew the syringe by holding the top of the needle and turning the syringe counter clockwise.

Return the syringe to an upright position.



- f) Place the 18 gauge blunt-tip vial access needle and the vial in a sharps container.

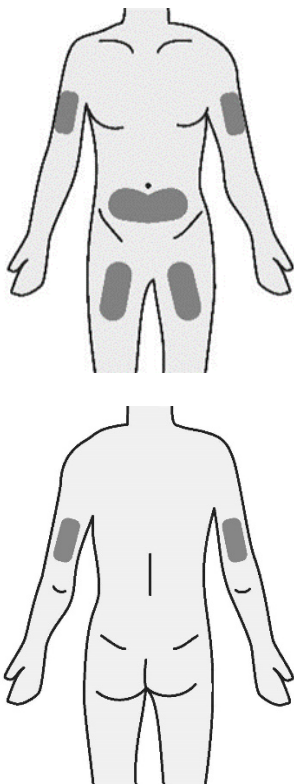


- g) Screw the 27 gauge x 13 mm pointed-tip injection needle to the syringe.

Important: Do not remove the needle cap from the needle when attaching to the syringe.

Do not use the blunt tip vial access needle to inject TAKHZYRO as this may cause pain and bleeding.

Step 4: Select and prepare injection site

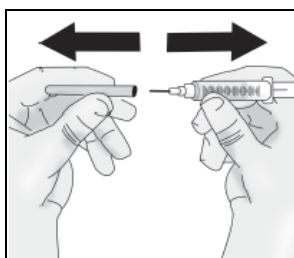


- a) Choose an injection site on your stomach (abdomen), thigh, or upper arm. The injection should be given subcutaneously.
- b) Clean your injection site with an alcohol wipe and allow the skin to dry completely.

Important:

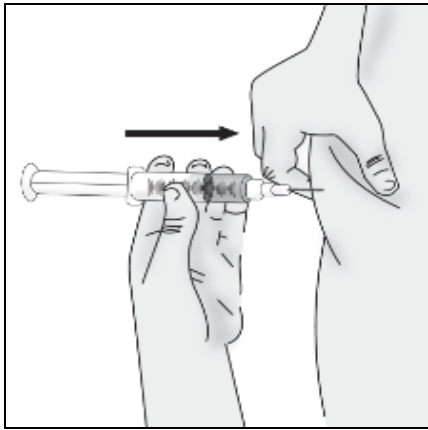
- It is important to use different injection sites to keep skin healthy.
- The area you choose for injection should be at least 5 cm away from any scars or your belly button (navel). Do not choose an area that is bruised, swollen, or painful.
- The outer area of the upper arm is not recommended if you are injecting yourself.

Step 5: Inject TAKHZYRO



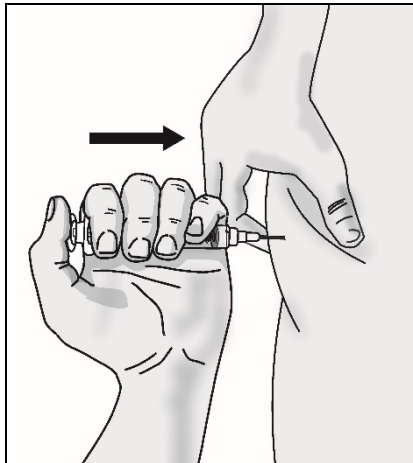
- c) Pull off the needle cap straight from the syringe without touching the needle. Do not pull on the plunger. Do not touch the needle tip or allow it to touch any other surface.

Important: Inject TAKHZYRO within 2 hours of preparing the dosing syringe at room temperature. Alternatively, you can place the dosing syringe in a refrigerator at 2°C to 8°C and you must use it within 8 hours.

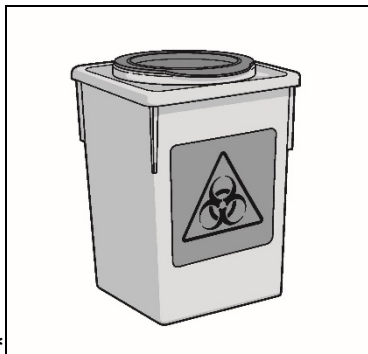


- d) Gently pinch about 3 cm of skin at your cleaned injection site and insert the needle.

Important: Be sure to inject into a subcutaneous space which is not too shallow (skin layer) or too deep (muscle).



- e) Push the plunger slowly until all the medicine has been injected. Release the skin fold and gently remove the needle. Do not recap the needle.



- f) Place the 27 gauge x 13 mm pointed-tip injection needle and the syringe in a sharps container.