

## Package leaflet: Information for the user

### TAKHZYRO 300 mg solution for injection in pre-filled syringe

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 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 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 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**

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 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 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](http://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.

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**

Shire Pharmaceuticals Ireland Limited  
Blocks 2 & 3 Miesian Plaza  
50-58 Baggot Street Lower  
Dublin 2  
Ireland  
Tel: +80066838470  
E-mail: [medinfoEMEA@shire.com](mailto:medinfoEMEA@shire.com)

This leaflet was last revised in 07/2020.

### **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 Instructions for Use before injecting TAKHZYRO. Contact your healthcare provider if you have any questions.

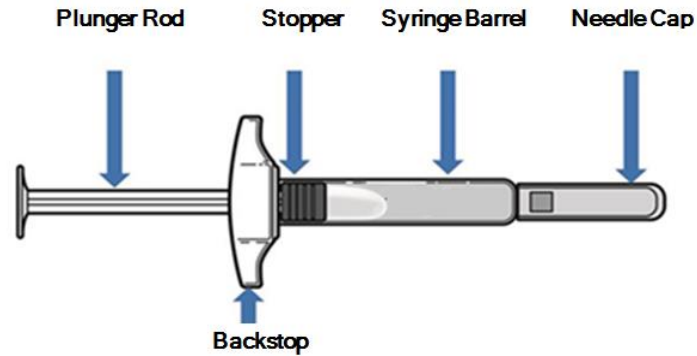
### **Intended use**

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.

### **Storing TAKHZYRO**

- Store TAKHZYRO 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.
- Store TAKHZYRO in the original carton to protect the pre-filled syringe from light.
- **Do not** shake TAKHZYRO.
- **Keep TAKHZYRO and all medicines out of the reach of children.**

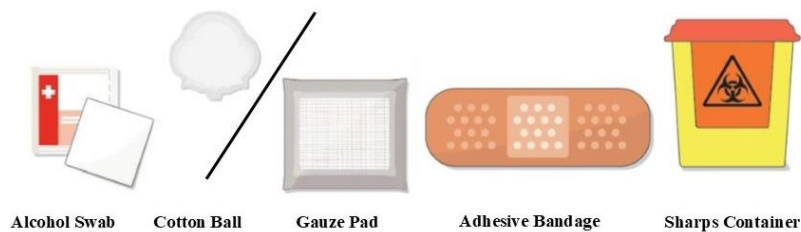
**Parts of Your TAKHZYRO Pre-filled Syringe Before Use (Figure A).**



**Figure A**

**STEP 1: Prepare for your injection**

- a. Gather an alcohol swab, cotton ball/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.



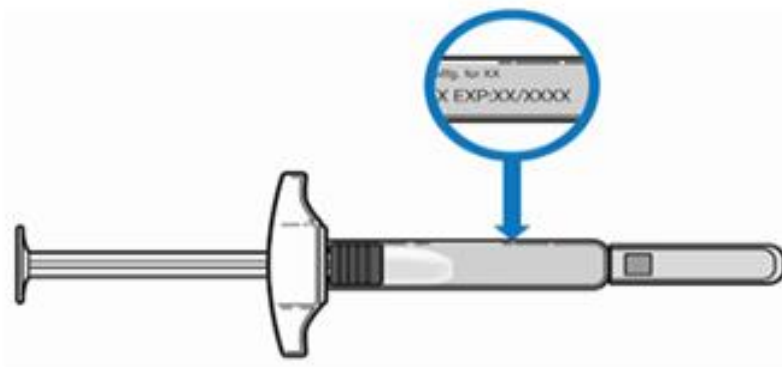
**Figure B**

- b. Remove TAKHZYRO from refrigerator, open the carton box and remove the TAKHZYRO pre-filled syringe from the tray.
- **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 to 30 minutes.**
  - Your medicine is sensitive to warm temperatures. **Do not** use external heat sources such as hot water to warm your TAKHZYRO pre-filled syringe.
  - **Do not** remove the needle cap until you are ready to inject.
- c. Wash your hands with soap and water. Dry your hands completely (**Figure C**).



**Figure C**

- d. **Check the expiration date on the label (Figure D).**
- **Do not** use TAKHZYRO pre-filled syringe if the expiration date has passed.

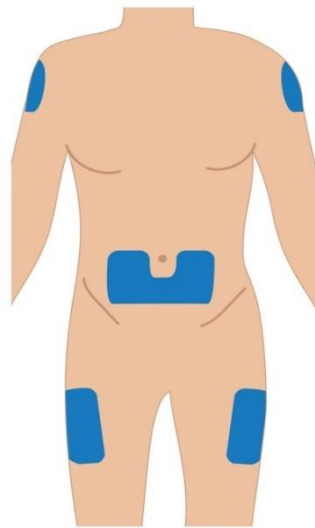


**Figure D**

- e. **Visually inspect** the TAKHZYRO pre-filled syringe for any damage and make sure the medicine is colourless to slightly yellow.
- **Do not** use product if syringe is damaged – e.g., cracked syringe.
  - **Do not** administer if the medicine is discoloured, cloudy or has flakes or particles in it and call your Healthcare Provider.
  - You might see air bubbles in the TAKHZYRO pre-filled syringe. This is normal and will not affect your dose.

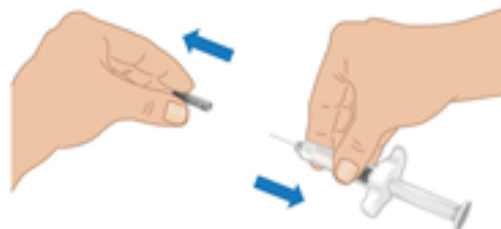
**STEP 2: Select and prepare your injection site**

- a. The TAKHZYRO pre-filled syringe should be injected into your stomach (abdomen), thigh, or the back of the upper arm (the outer area of the upper arm is not recommended if you are injecting yourself) (**Figure E**).
- It is important to rotate injection sites to keep skin healthy. Each new injection should be given at least 3 cm from the last site you used.
  - **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 E**

- b. Clean the injection site with an alcohol swab and allow it to dry.
- **Do not** fan or blow on the clean site.
  - **Do not** touch this area again before giving your injection.
- c. Remove 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 (**Figure F**).
- **Do not** recap your TAKHZYRO pre-filled syringe.
  - **Do not** use the TAKHZYRO pre-filled syringe if it has been dropped without the needle cap on or if the needle looks damaged or bent.
  - **Do not** touch the needle or allow the needle to touch anything.



**Figure F**

### **STEP 3: Inject TAKHZYRO**

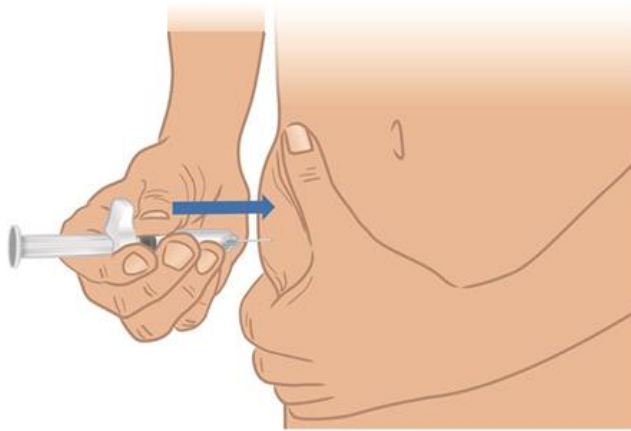
- a. Grip the TAKHZYRO pre-filled syringe in one hand like a pencil. Avoid touching the needle or pushing on the plunger (**Figure G**).





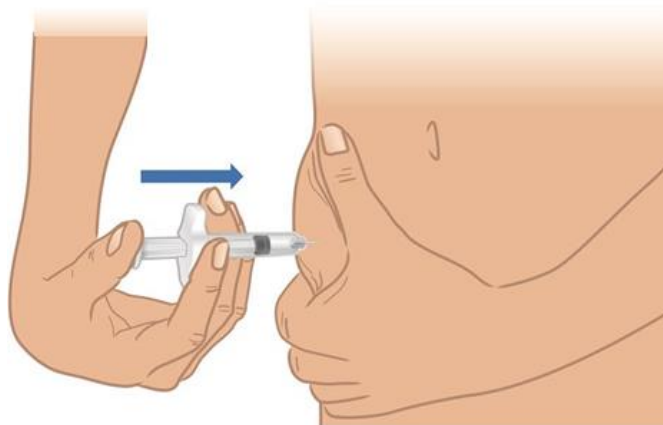
**Figure G**

- b. With your other hand, gently pinch about 3 cm fold of skin at the cleaned injection site.
- c. With one quick, short motion, push needle all the way into skin. Make sure to keep the needle in place (**Figure H**).



**Figure H**

- d. **Slowly push** the plunger until all of the liquid is injected and the syringe is empty, then gently let go of your skin.
- e. Slowly withdraw needle while maintaining the syringe at the same angle (**Figure I**).



**Figure I**

- 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 your used TAKHZYRO pre-filled syringe.

- **Do not** touch the needle.
- To avoid a needle-stick injury, **do not** recap the needle.
- Put your used TAKHZYRO pre-filled syringes in a sharps disposal container right away after use.
- **Do not** reuse the TAKHZYRO pre-filled syringe and any of your injection supplies.

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