

TAKHZYRO®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

- ▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I using TAKHZYRO?

TAKHZYRO contains the active ingredient lanadelumab. TAKHZYRO is used in patients aged 2 years and older to prevent angioedema attacks in hereditary angioedema (HAE). For more information, see Section [1. Why am I using TAKHZYRO?](#) in the full CMI.

2. What should I know before I use TAKHZYRO?

Do not use if you have ever had an allergic reaction to TAKHZYRO or any of the ingredients listed at the end of the CMI. Do not give TAKHZYRO to a person below 2 years of age.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. Tell your doctor if you are using TAKHZYRO before you have laboratory tests to measure how well your blood is clotting. For more information, see Section [2. What should I know before I use TAKHZYRO?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with TAKHZYRO and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use TAKHZYRO?

- TAKHZYRO should be used exactly as your doctor has told you
- TAKHZYRO must be injected under the skin (subcutaneously).

More instructions can be found in Section [4. How do I use TAKHZYRO?](#) in the full CMI.

5. What should I know while using TAKHZYRO?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist
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	<p>you visit that you are using TAKHZYRO.</p>
<p>Things you should not do</p>	<ul style="list-style-type: none"> • Do not stop using this medicine or change the dosage without checking with your doctor.
<p>Driving or using machines</p>	<ul style="list-style-type: none"> • TAKHZYRO has negligible influence on the ability to drive or use machines • Do not drive or use machines if you feel dizzy after using TAKHZYRO.
<p>Looking after your medicine</p>	<ul style="list-style-type: none"> • Store at 2°C - 8°C in a refrigerator for the duration of its shelf life. Do not freeze. • TAKHZYRO pre-filled syringe removed from refrigeration should be stored below 25°C and used within 14 days. Do not return pre-filled syringes to refrigeration after storage at room temperature

For more information, see Section [5. What should I know while using TAKHZYRO?](#) in the full CMI.

6. Are there any side effects?

Serious side effects: allergic reactions which may result in shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; or rash, itching or hives on the skin. Common side effects include injection site reactions (including pain, skin redness, bruising, discomfort, swelling, bleeding, itching, hardening of skin, tingling, warmth and rash), dizziness or feeling faint, muscle pain, raised skin rash, allergic reactions (including itching, discomfort, tingling, of the tongue), abnormal liver-related blood test results.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

- ▼ This medicine is subject to additional monitoring due to approval of an extension of indications. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

TAKHZYRO®

Active ingredient(s): *lanadelumab*

Consumer Medicine Information (CMI)

This leaflet provides important information about using TAKHZYRO. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using TAKHZYRO.**

TAKHZYRO is a new medicine. Please check with your doctor whether there is any additional information about this medicine that you should know since you were last treated with this medicine.

Where to find information in this leaflet:

- [1. Why am I using TAKHZYRO?](#)
- [2. What should I know before I use TAKHZYRO?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use TAKHZYRO?](#)
- [5. What should I know while using TAKHZYRO?](#)
- [6. Are there any side effects?](#)

1. Why am I using TAKHZYRO?

TAKHZYRO contains the active ingredient lanadelumab. It 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 associated with HAE.

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

2. What should I know before I use TAKHZYRO?

Warnings

Do not use TAKHZYRO if:

you are allergic to lanadelumab, or any of the ingredients listed at the end of this leaflet. When using TAKHZYRO for the first time, check the ingredients to make sure you can use the medicine.

Do not give this medicine to a person below 2 years of age.

Check with your doctor 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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

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

TAKHZYRO may affect other medicines or be affected by them. Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

4. How do I use TAKHZYRO?

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, especially if you have a low body weight
- 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.
- If you are not sure how much and how frequently you need to inject TAKHZYRO, ask your doctor, pharmacist, or nurse

How to use TAKHZYRO

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor, pharmacist, or nurse for help.

TAKHZYRO should be injected under the skin (subcutaneously).

The injection can be self-administered or given by another person, for example your carer, your doctor, his/her assistant or your nurse.

If you are injecting the medicine yourself, you must receive adequate training by your doctor or nurse. You will find detailed instructions for injections at the end of this leaflet.

Instructions for administering TAKHZYRO

Important information

Read the leaflet carefully before using TAKHZYRO.

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):

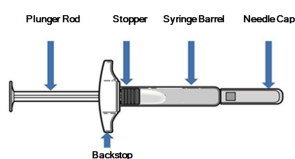


Figure A

STEP 1: Prepare for your injection

1.1 Gather a sharps disposal container, alcohol swab, cotton ball/gauze pad and adhesive bandage. Place them on a clean, flat surface in a well-lighted area. These items are not included in the TAKHZYRO pack.

1.2 Take out the TAKHZYRO pack from the 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 temperature. 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 the medicine.

1.3 Wash your hands with soap and water (Figure B). Dry your hands completely.



Figure B

1.4 Check the expiry date on the label (Figure C).

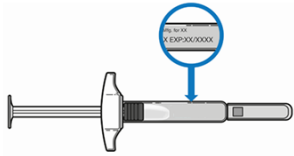


Figure C

- Do not use the TAKHZYRO pre-filled syringe if the expiry date has passed.

1.5 Visually inspect the TAKHZYRO pre-filled syringe for any damage and make sure the medicine is colourless to slightly yellow.

- Do not use it if the syringe is damaged (e.g., cracked syringe)
- Do not use it if the solution 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.
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STEP 2: Select and prepare your injection site

2.1 The TAKHZYRO pre-filled syringe should be injected into your stomach (abdomen), thigh, or the back of the upper arm (only if a caregiver is giving you the injection) (Figure D).

- It is important to rotate injection sites to keep skin healthy. Each new injection should be given at least 2.5 cm (1 inch) 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 (2 inches) away from any scars or your belly button (navel)

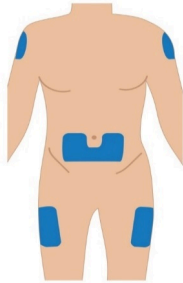


Figure D

2.2 Clean the injection site with an alcohol swab and allow it to dry

- Do not fan or blow on the cleaned site
- Do not touch this area again before giving your injection.

2.3 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 TAKHZYRO pre-filled syringe with the other hand (Figure E). Throw away the needle cap.

- 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.

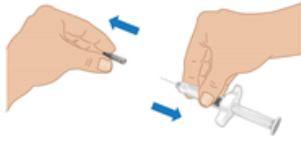


Figure E

STEP 3: Inject TAKHZYRO

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



Figure F

3.2 With your hand, gently pinch a 2.5 cm (1 inch) fold of skin at the cleaned injection site.

3.3 Using a quick dart-like motion, insert the needle. Make sure to keep the needle in place (Figure G).

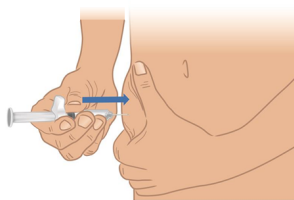


Figure G

3.4 Slowly push the plunger until all of the liquid is injected and the syringe is empty, then gently let go of your skin.

3.5 Slowly withdraw the needle while maintaining the syringe at the same angle (Figure H).

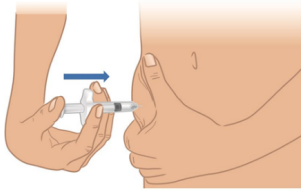


Figure H

3.6 Press cotton ball or gauze pad over the 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 the injection site with an adhesive bandage if needed.

3.7 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 syringe in a sharps disposal container right away after use
- Do not reuse the TAKHZYRO pre-filled syringe and any of your injection items.

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

If you forget to use TAKHZYRO

If you forget to use this medicine (or cannot inject it at your usual time), use it as soon as possible 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 have trouble remembering to use your medicine, ask your pharmacist or nurse for some hints.

If you use too much TAKHZYRO

If you think that you have used too much TAKHZYRO, you may need urgent medical attention.

You should immediately:

- **phone the Poisons Information Centre (Australia: 13 11 26; New Zealand: 0800 POISON or 0800 764766) for advice, or**
- **go to the Accident and Emergency Department at your nearest hospital.**

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using TAKHZYRO?

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using TAKHZYRO.

Tell any other doctors, dentists, and pharmacists who treat you that you are using this medicine.

If you become pregnant while using this medicine, tell your doctor immediately.

It is strongly recommended that every time you inject a dose of TAKHZYRO, write down the date and batch number of the medicine. This is so that you keep a record of the batches used in case you have a severe allergic reaction to TAKHZYRO.

Things you must not do

Do not use TAKHZYRO to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop using your medicine or change the dosage without checking with your doctor.

Driving or using machines

Be careful driving or operating machinery until you know how TAKHZYRO affects you.

Do not drive or use machines if you feel dizzy after using TAKHZYRO.

Looking after your medicine

Keep your medicine in the original carton to protect the pre-filled syringe from light until it is time to use it.

If you take the medicine out of the pack it may not keep well.

Keep the medicine in the refrigerator at 2°C to 8°C. Do not freeze it.

TAKHZYRO pre-filled syringe removed from refrigeration should be stored below 25°C and used within 14 days. Do not return pre-filled syringes to refrigerated storage after storage at room temperature.

Do not shake TAKHZYRO.

Do not store TAKHZYRO or any other medicine in the bathroom or near a sink. Do not leave it on a windowsill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">● Reactions where the injection is given - symptoms include: pain, skin redness, bruising, discomfort, swelling, bleeding, itching, hardening of skin, tingling, warmth and rash● Dizziness, feeling faint● Muscle pain● Raised skin rash● Allergic reactions including itching, discomfort, tingling of the tongue	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> • Abnormal liver-related blood test results 	

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • Allergic reaction which may result in shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; or rash, itching, or hives on the skin 	<p>Contact your doctor or go to the Accident and Emergency Dept. at the nearest hospital immediately if any of these serious side effects occur</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What TAKHZYRO contains

Active ingredient	Lanadelumab
Other ingredients	<ul style="list-style-type: none">• Dibasic sodium phosphate dihydrate• Citric acid monohydrate• Histidine• Sodium chloride• Polysorbate 80• Water for injections

Do not take this medicine if you are allergic to any of these ingredients.

What TAKHZYRO looks like

TAKHZYRO, a ready-to-use solution for injection under the skin (subcutaneous injection), is supplied in a single-dose, pre-filled glass 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.

TAKHZYRO solution is colourless to slightly yellow in colour.

Each pack contains one pre-filled syringe fitted with a 27-gauge needle for injection (see 'Instructions for administering TAKHZYRO' above).

(AUST R 330280 and 409942).

Who distributes TAKHZYRO

Australia:

Takeda Pharmaceuticals Australia Pty Ltd

Level 39, 225 George Street

Sydney NSW 2000

Australia

Telephone: 1800 012 612

www.takeda.com/en-au

New Zealand:

Takeda New Zealand Limited

Level 10, 21 Queen Street

Auckland 1010

New Zealand

Telephone: 0508 169 077

www.takeda.com/en-au

This leaflet was prepared in July 2024.

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