

- ▼ 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. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

TAKHZYRO®

Pre-filled Syringe

lanadelumab

Consumer Medicine Information

What is in this leaflet

Please read this leaflet before you start using TAKHZYRO.

This leaflet answers some common questions about TAKHZYRO. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

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.

All medicines have risks and benefits. Your doctor has weighed the risks of you using TAKHZYRO against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What TAKHZYRO is used for

TAKHZYRO is a medicine used in adults, and adolescents aged 12 years and older to prevent angioedema attacks in hereditary angioedema (HAE).

You may still experience acute HAE attacks whilst using TAKHZYRO. You should make sure that you carry acute attack treatment and that you use this treatment as advised by your doctor.

HAE is a hereditary condition which means it can run in families. It happens when your blood does not have enough of a protein called 'C1 esterase inhibitor' (or 'C1 inhibitor'), or it 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.

TAKHZYRO contains the active substance 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.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

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

Before you use TAKHZYRO

When you must not use it

Do not use TAKHZYRO if you have an allergy to:

- any medicine containing lanadelumab
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

It is important to be able to tell when you might be having an allergic reaction as the symptoms are very similar to those of an attack of HAE, so you should discuss this with your doctor.

Do not give this medicine to a person below 12 years of age.

The benefits and risks in children below 12 years of age have not been established.

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start using this medicine, talk to your doctor.

Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

There is no information on the safety of TAKHZYRO use during pregnancy or breastfeeding. Your doctor can discuss with you the risks and benefits involved.

Tell 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.

If you have not told your doctor about any of the above, tell him/her before you start using TAKHZYRO.

Taking other medicines

Tell your doctor or pharmacist if you are using any other medicines, including any that you get 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.

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.

How much 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.

If you are not sure how much and how frequently you need to inject TAKHZYRO, ask your doctor, pharmacist or nurse.

How to use it

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.

How long to use it

Continue using this medicine for as long as your doctor prescribes it for you.

Do not stop using this medicine without consulting your doctor, as a sudden stop may not control your symptoms well.

If you forget to use it

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.

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 (overdose)

Immediately telephone your doctor or the Poisons Information Centre (Australia: 13 11 26; New Zealand: 0800 POISON or 0800 764766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have used too much TAKHZYRO. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are 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.

Things to be careful of

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.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using TAKHZYRO.

Like all medicines, TAKHZYRO can cause some side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- 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
- abnormal liver-related blood test results.

The above list includes the more common side effects of your medicine.

Contact your doctor or go to the Accident and Emergency at the nearest hospital immediately if any of the following occurs:

- 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.

Tell your doctor, pharmacist or nurse if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using TAKHZYRO

Storage

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 window sill 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.

Disposal

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.

Product description

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 300 mg of lanadelumab in 2 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' below).

Ingredients

Active ingredient: lanadelumab

Other ingredients:

- dibasic sodium phosphate dihydrate
- citric acid monohydrate
- histidine
- sodium chloride
- polysorbate 80
- water for injections

Sponsor

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

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Australian Registration Number:

300 mg/2 mL pre-filled syringe: AUST R 330280

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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):

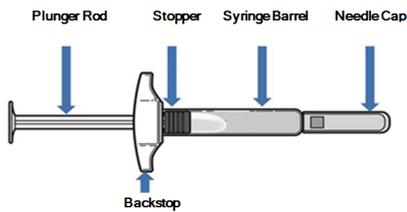


Figure A

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).

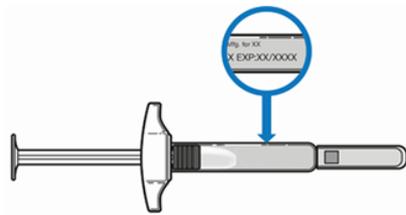


Figure C

- 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.

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 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).

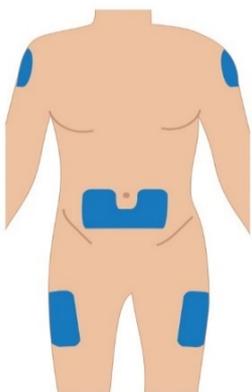


Figure D

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 the 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.

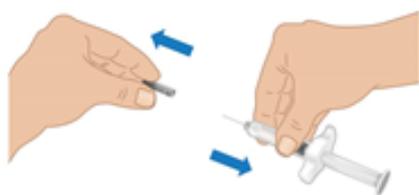


Figure E

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 other 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).

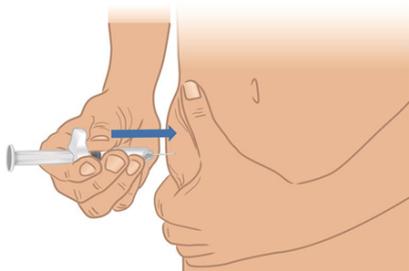


Figure G

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).

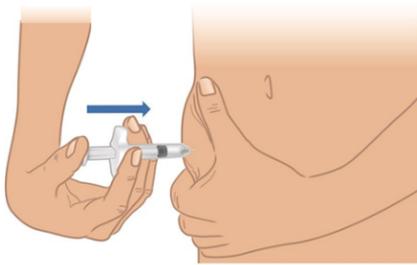


Figure H

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.