

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.

1. Why am I using FIRAZYR?

FIRAZYR contains the active ingredient icatibant acetate. FIRAZYR is used to treat the symptoms of an acute attack of hereditary angioedema (HAE).

For more information, see Section [1. Why am I using FIRAZYR?](#) in the full CMI.

2. What should I know before I use FIRAZYR?

Do not use if you have ever had an allergic reaction to FIRAZYR or any of the ingredients listed at the end of the CMI.

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.

For more information, see Section [2. What should I know before I use FIRAZYR?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with FIRAZYR 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 FIRAZYR?

- FIRAZYR is given in a ready-to-use syringe as subcutaneous injection into the fatty tissue under the skin in the abdomen.
- Injections are usually administered by healthcare professionals.
- The recommended dose as soon as you develop symptoms of an angioedema attack is one injection of 3 mL (30 mg in 3 mL) for adults and one injection of 1 mL for children and adolescents aged 2 to 17 years.

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

5. What should I know while using FIRAZYR?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using FIRAZYR.• Tell your doctor immediately if you notice that your symptoms of the attack get worse after you use FIRAZYR.
Driving or using machines	<ul style="list-style-type: none">• Do not drive or operate any machinery if you feel tired or dizzy as a result of your HAE attack or after using FIRAZYR.
Looking after your medicine	<ul style="list-style-type: none">• Keep the medicine in a cool dry place where the temperature stays below 25°C. Do not freeze it.

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

6. Are there any side effects?

Common side effects include a reaction at the site of the injection such as burning sensations, erythema, pain, swelling, feeling of warmth and itching. Apart from symptoms at the site of the injection, the most common side effects include nausea, pain in the abdomen, weakness, dizziness, headache, blocked nose, rash, vomiting, fatigue, fever, sore throat, weight gain, asthma, cough, itching, redness of the skin, hot flushes, muscle spasm, hives and sign of altered liver function.

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.

FIRAZYR

Active ingredient(s): *icatibant acetate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using v. **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 FIRAZYR.**

Where to find information in this leaflet:

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

1. Why am I using FIRAZYR?

FIRAZYR contains the active ingredient icatibant acetate. During attacks of hereditary angioedema (HAE), levels of a substance in your bloodstream called bradykinin are increased and this leads to symptoms like swelling, pain, nausea, and diarrhoea. FIRAZYR blocks the activity of bradykinin and therefore, helps reduce the symptoms of an HAE attack.

FIRAZYR is used to treat the symptoms of an acute attack of hereditary angioedema (HAE) in adults, adolescents and children aged 2 years and older.

2. What should I know before I use FIRAZYR?

Warnings

Do not use FIRAZYR if:

- you are allergic to icatibant acetate, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

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.

Check with your doctor if you:

- are suffering from angina (reduced blood flow to the heart muscle)
- you have recently suffered a stroke
- 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. You should not breastfeed for 12 hours after you have used FIRAZYR. It is not known whether FIRAZYR passes into your breast milk.

Use in children and adolescents

- Do not give FIRAZYR to a child under 2 years of age or weighing less than 12 kg.

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.

Tell your doctor before using FIRAZYR if you are taking a medicine known as an Angiotensin Converting Enzyme (ACE) inhibitor (for example: captopril, enalapril, ramipril, quinapril, lisinopril) which is used to lower your blood pressure or for any other reason. FIRAZYR can interact with ACE inhibitors.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect FIRAZYR.

4. How do I use FIRAZYR?

How much to use

Adults

- The recommended dose of FIRAZYR in adults is one injection (30 mg in 3 mL)
- If the HAE symptoms are still present, or return after initial relief, an additional injection of FIRAZYR (3 mL) may be given after 6 hours.
- If after a further 6 hours you still experience symptoms you may need a third injection of FIRAZYR (3 mL).
- Your doctor will determine the exact dose of FIRAZYR and will tell you how often it should be used.
- Follow the instructions provided and use FIRAZYR until your doctor tells you to stop.

You should have no more than 3 injections in a 24-hour period and no more than 8 injections in a month.

Children and adolescents aged 2 to 17 years

- The recommended dose of FIRAZYR is one injection of 1 mL up to a maximum of 3 mL.
- The dose will be determined by your doctor based on your child's body weight.

When to use FIRAZYR

- FIRAZYR should be used as soon as you develop symptoms of an angioedema attack (e.g. increased skin swelling, particularly affecting the face and neck, increasing tummy pain).
- In case of insufficient relief or recurrence of symptoms, up to 3 injections can be administered spread over a period of 24 h.

How to use FIRAZYR pre-filled syringe

FIRAZYR comes in a ready-to-use syringe. A needle is packed separately which you need to attach before use. Each syringe should only be used once.

FIRAZYR injections are usually administered by healthcare professionals. Initial treatment should be given in a medical institution or under the guidance of a physician. The decision to initiate caregiver or self-administration of FIRAZYR should only be made by a physician experienced in the diagnosis and treatment of HAE.

You or a caregiver must be trained on subcutaneous injection technique before you self-inject, or a caregiver injects you or a child with FIRAZYR.

- Immediately after you self-inject or a caregiver injects you or a child with FIRAZYR while experiencing a laryngeal attack (obstruction of the upper airway), seek medical care in a medical institution.
- If the HAE attack has not shown signs of improvement within 2 hours of the injection of FIRAZYR; or if the attack spreads to face, lips, throat, or voice box, or it causes any difficulty breathing, contact the doctor or hospital immediately.

Step-by-step instructions for injecting FIRAZYR

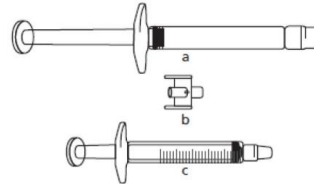
1. General information

- Clean the work area to be used before beginning the process.
- Wash your hands with soap and water.
- Open the blister tray by peeling back the seal.
- Remove the pre-filled syringe from the blister tray.
- Check the pre-filled syringe if there are any visible signs of deterioration. The medicine inside your should be clear and colourless. **Do not use your FIRAZYR pre-filled syringe if the solution contains particles, is cloudy, or has an unusual colour.**
- Remove the cap from the end of the pre-filled syringe by unscrewing the cap.
- Put down the pre-filled syringe after unscrewing the cap.

2a). Preparing the syringe for children and adolescents (2-17 years) weighing 65 kg or less (important information for healthcare professionals and caregivers)

Where the dose is less than 30 mg (3 mL), the following equipment is required to extract the appropriate dose:

- FIRAZYR pre-filled syringe (containing icatibant solution)
- Adapter (connector)
- 3 mL graduated syringe



The required injection volume in mL should be drawn up in an empty 3 mL graduated syringe (see table below).

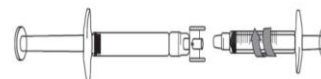
Table 1. Dosage regimen for children and adolescents:

Body weight	Injection volume
12 kg to 25 kg	1.0 mL
26 kg to 40 kg	1.5 mL
41 kg to 50 kg	2.0 mL
51 kg to 65 kg	2.5 mL

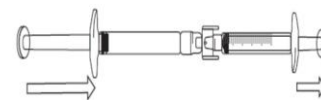
Patients weighing more than 65 kg will use the full contents of the pre-filled syringe (3 mL).

Extracting dose less than 3 mL and transferring FIRAZYR solution to the graduated syringe

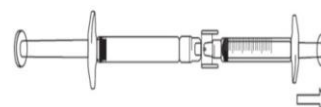
- Remove the caps on each end of the adapter (avoid touching the ends of the adapter and syringe tips, to prevent contamination).
- Screw the adapter onto the pre-filled syringe.
- Attach the graduated syringe to the other end of the adapter ensuring that both connections fit securely.



- To start transfer of FIRAZYR solution, push the pre-filled syringe plunger (on far left of the below image).

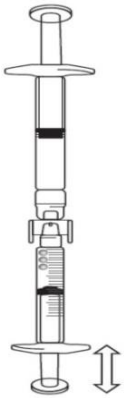


- If the FIRAZYR solution does not begin to transfer to the graduated syringe, pull slightly on the graduated syringe plunger until the FIRAZYR solution starts to flow into the graduated syringe (see below image).



- Continue to push on the pre-filled syringe plunger until the required injection volume (dose) is transferred to the graduated syringe. See Table 1 for dosage information.

- If there is air in the graduated syringe:
- Turn the connected syringes so that the pre-filled syringe is on top (see below image).



- Push the plunger of the graduated syringe so that any air is transferred back into the pre-filled syringe (this step may need to be repeated several times).
- Withdraw the required volume of FIRAZYR solution.
- Remove the pre-filled syringe and adapter from the graduated syringe and discard the pre-filled syringe and adapter into the sharp's container.

2b). Preparing the syringe and needle for injection: All patients (adults, adolescents and children)

- Remove the needle cap from the blister tray.
- Twist the lid of the needle cap to break the seal (the needle should be still in the needle cap).

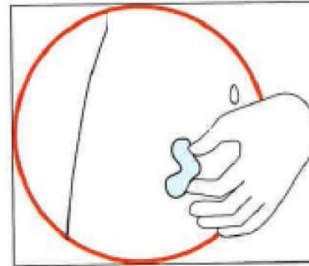


- Grip the syringe firmly. Carefully attach the needle to the syringe containing the colourless solution.
- Screw the syringe on the needle still fixed in the needle cap.
- Remove the needle from the needle cap by pulling the syringe. Do not pull up on the plunger.
- The syringe is now ready for injection.



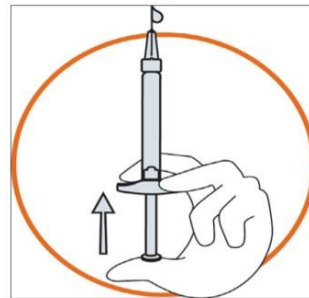
3. Preparing the injection site

- Choose the injection site. The injection site should be a skin fold on your abdomen, approximately 5 to 10 cm below your navel on either side. This area should be at least 5 cm away from any scars. Do not choose an area that is bruised, swollen, or painful.
- Clean the injection site with an alcohol wipe and allow it to dry.

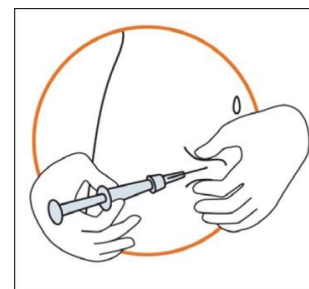


4. Injecting the solution

- Hold the syringe in one hand between two fingers with your thumb at the bottom of the plunger.
- Make sure that there is no air bubble in the syringe by pressing the plunger until the first drop appears on the tip of the needle.



- Hold the syringe between a 45 to 90 degrees angle to your skin with the needle facing the skin.
- Keeping the syringe in one hand, use your other hand to gently hold a fold of skin between your thumb and fingers at the previously disinfected injection site.
- Hold the fold of the skin, bring the syringe to the skin and quickly insert the needle into the skin fold.
- Slowly push the plunger of the syringe with a steady hand until all the solution is injected into the skin and no liquid remains in the syringe.
- Press slowly so that this takes approximately 30 seconds.
- Release the skin fold and gently pull the needle out.



5. Disposal of the injection material

- Discard the syringe, needle and needle cap into the sharp's container.

- Ask your pharmacist if you are not sure about the right way to throw away used syringes and needles.

If you use too much FIRAZYR

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

You should immediately:

- phone the National Poisons Centre (telephone **0800 POISON** or **0800 764766**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

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

When high doses have been given, patients have experienced a drop in blood pressure.

5. What should I know while using FIRAZYR?

Things you should do

Tell your doctor immediately if you notice that the symptoms of the attack get worse after you use FIRAZYR.

Some of the side effects connected with FIRAZYR are similar to the symptoms of the HAE attack.

Call your doctor straight away if:

- the HAE attack involves face, lips, throat, or voice box, or any difficulty breathing.
- after injection with FIRAZYR you/the child experience(s) a laryngeal attack (obstruction of the upper airway).
- the HAE attack has not shown signs of improvement within 2 hours of the injection of FIRAZYR.

Remind any doctor, dentist or pharmacist [add other health professionals as appropriate] you visit that you are using FIRAZYR.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how FIRAZYR affects you.

FIRAZYR may cause dizziness and dizziness in some people

Looking after your medicine

- Keep your medicine in the pack until it is time to use it.
- Keep the medicine in a cool dry place where the temperature stays below 25°C. Do not freeze it.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

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
<p>Reaction at the site of injection:</p> <ul style="list-style-type: none"> • burning sensations • reddening of the skin (erythema) • pain, swelling • feeling of warmth • itching (pruritus) <p>Other common side effects</p> <ul style="list-style-type: none"> • nausea • pain in the abdomen (tummy) • weakness • dizziness • headache • blocked nose • rash • vomiting • fatigue • fever • sore throat • weight gain • asthma • cough • itching • redness of the skin • hot flushes • muscle spasm • hives • abnormal liver function test (symptoms may include yellowing of the skin and eyes (jaundice)). 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> <p>These are the more common side effects of FIRAZYR, usually mild and short-lived.</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

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit-risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions at <https://pophealth.my.site.com/carmreportnz/s/>

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 FIRAZYR contains

Active ingredient (main ingredient)	icatibant acetate
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• sodium chloride• acetic acid - glacial• sodium hydroxide• water for injections.

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

What FIRAZYR looks like

FIRAZYR is supplied in one single-use pre-filled glass syringe with a grey plunger stopper. The solution is clear and colourless and free from visible particles. A hypodermic needle (25 G; 16 mm) is included in the package.

Who distributes FIRAZYR in New Zealand:

Takeda New Zealand Limited
Level 10
21 Queen Street
Auckland 1010
New Zealand
Telephone: 0508 169 077

<https://www.takeda.com/en-nz/>

This leaflet was prepared in February 2026.

FIRAZYR and FIRAZYR logo are registered trademarks of Shire Orphan Therapies GmbH.