

FIRAZYR SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE 30MG/3ML

Icatibant (30mg)

What is in this leaflet

1. What FIRAZYR is used for
2. How FIRAZYR works
3. Before you use FIRAZYR
4. How to use FIRAZYR
5. While you are using it
6. Side effects
7. Storage and Disposal of FIRAZYR
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of RiMUP revision
11. Serial number

What FIRAZYR is used for

FIRAZYR contains the active substance icatibant.

FIRAZYR is used for treating the symptoms of hereditary angioedema (HAE) in adults, adolescents and children aged 2 years and older.

How FIRAZYR works

In 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 ends the further progression of the symptoms.

Before you use FIRAZYR

- When you must not use it

Do not take this medicine if:

- you are allergic to icatibant or any other ingredients of this medicine (listed in Product Description)

- Before you start to use it

Check with your doctor or pharmacist before taking FIRAZYR if you:

- are suffering from angina (reduced blood flow to the heart muscle)
- have recently suffered a stroke

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

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

In addition:

- You or your caregiver must be trained on subcutaneous (under the skin) injection technique before you self-inject or your caregiver injects you with FIRAZYR.
- Immediately after you self-inject FIRAZYR or your caregiver injects you with FIRAZYR while you are experiencing a laryngeal attack (obstruction of the upper airway), you must seek medical care in a medical institution.
- If your symptoms are not resolved following one self- or caregiver administered injection of FIRAZYR, you should seek medical advice regarding additional injections of FIRAZYR. For adult patients, up to 2 additional injections may be given within 24 hours.

Pregnancy and lactation

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor before starting to use FIRAZYR.

If you are breast-feeding you should not breast-feed for 12 hours after you have last received FIRAZYR.

Children and adolescents

FIRAZYR is not recommended for use in children under 2 years of age or weighing less than 12 kg because it has not been studied in these patients.

- Taking other medicines

Tell your doctor if you are taking, have recently taken or might take any other medicines.

FIRAZYR is not known to interact with other medicines. 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, you should inform your doctor before receiving FIRAZYR.

How to use FIRAZYR

Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

If you have never received FIRAZYR previously, your first dose of FIRAZYR will always be injected by your doctor or nurse. Your doctor will tell you when it is safe for you to go home. After discussion with your doctor or nurse and after training in subcutaneous (under the skin) injection technique, you may be able to inject yourself with FIRAZYR or your caregiver may inject FIRAZYR for you when you have an HAE attack. It is important that FIRAZYR is injected subcutaneously (under the skin) as soon as you notice an attack of angioedema. Your healthcare provider will teach you and your caregiver how to safely inject FIRAZYR by following the instructions in the Package Leaflet.

- How much to use

Your doctor has determined the exact dose of FIRAZYR and will tell you how often it should be used.

Adults

- The recommended dose of FIRAZYR is one injection (3 ml, 30 mg) injected subcutaneously (under the skin) as soon as you notice the attack of angioedema (for example increased skin swelling, particularly affecting the face and neck, or increasing tummy pain).

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 based on body weight injected subcutaneously (under the skin) as soon as you develop

symptoms of an angioedema attack (for example increased skin swelling, particularly affecting the face and neck, increasing tummy pain). - See section on instructions for use for the dose to inject. - If you are not sure which dose to inject, ask your doctor, pharmacist or nurse. - <u>When to use it</u> Use as directed by your doctor or pharmacist. - <u>How long to use it</u> Adults - If you experience no relief of symptoms after 6 hours, you should seek medical advice regarding additional injections of FIRAZYR. For adults, up to 2 additional injections may be given within 24 hours. - You should not have more than 3 injections in a 24 hour period and if you require more than 8 injections in a month, you should seek medical advice. Children and adolescents aged 2 to 17 years - If your symptoms get worse or do not improve, you must seek immediate medical help.	Do not give FIRAZYR to anyone else, even if they have the same symptoms or condition as you. - <u>Things to be careful of</u> <u>Driving and using machines</u> Do not drive or use machines if you feel tired or dizzy as a result of your HAE attack or after using FIRAZYR. Side effects Like all medicines, FIRAZYR can cause side effects, although not everybody gets them. Almost all patients receiving FIRAZYR will experience a reaction at the site of the injection (such as skin irritation, swelling, pain, itchiness, redness of the skin and burning sensation). These effects are usually mild and clear up without the need for any additional treatment. Very common (may affect more than 1 in 10 people): • Additional injection site reactions (pressure sensation, bruising, reduced sensation and/or numbness, raised itchy skin rash and warmth). Common (may affect up to 1 in 10 people): • Feeling sick • Headache • Dizziness • Fever • Itching • Rash • Skin redness • Abnormal liver function test Not known (frequency cannot be estimated from the available data): • Hives (urticaria) Tell your doctor immediately if you notice that the symptoms of your attack get worse after you received FIRAZYR. Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine. You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug	Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]. Storage and Disposal of FIRAZYR - <u>Storage</u> Keep out of the reach and sight of children. Do not use this medicine after the expiry date stated on the label after 'EXP'. The expiry date refers to the last day of that month. Store below 25°C. Do not freeze. Do not use this medicine if you notice that the syringe or needle packaging is damaged or if there are any visible signs of deterioration, for example if the solution is cloudy, if it has floating particles, or if the colour of the solution has changed. - <u>Disposal</u> Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.
While you are using FIRAZYR - <u>Things you must do</u> Use your medicine exactly as your doctor has told you. Tell all the doctors, dentists and pharmacists treating you that you are using FIRAZYR. Tell your doctor immediately if you become pregnant while using this medication. Take FIRAZYR only with a doctor's prescription. - <u>Things you must not do</u> Do not use any new medicines without consulting your doctor or pharmacist.		Product Description - <u>What it looks like</u> FIRAZYR is presented as a clear, colourless solution for injection in a pre-filled glass syringe of 3 ml. Hypodermic needle is included in the pack. FIRAZYR is available as a single pack containing one pre-filled syringe with one needle. - <u>Ingredients</u> - Active ingredient(s) Icatibant. Each pre-filled syringe contains 30 milligrams of icatibant (as acetate).

- Inactive ingredients
sodium chloride, acetic acid glacial,
sodium hydroxide and water for
injection.
- FIRAZYR contains sodium
The injection solution contains less
than 1 mmol (23 milligrams) of
sodium per syringe, so it is essentially
'sodium-free'.
- MAL number(s):
MAL*****

Manufacturer

Drug Product manufacturer:
Vetter Pharma-Fertigung GmbH & Co
KG
Schützenstrasse 87, 99-101
88212 Ravensburg
Germany

Batch release site:

Takeda Pharmaceuticals International AG
Ireland Branch
Block 2 Miesian Plaza,
50-58 Baggot Street Lower,
Dublin 2, D02 HW68
Ireland

Product Registration Holder

Takeda Malaysia Sdn Bhd
Unit TB-L13-1, Level 13,
Tower B, Plaza 33,
No. 1, Jalan Kemajuan,
Seksyen 13, 46200 Petaling Jaya,
Selangor, Malaysia

Date of revision

30/06/2026

Serial Number

NPRA (R1) 26/006

INSTRUCTIONS FOR USE

How should FIRAZYR be administered?

FIRAZYR is intended for subcutaneous injection (under the skin). Each syringe should only be used once.

FIRAZYR is injected with a short needle into the fatty tissue under the skin in the abdomen (tummy).

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

The following step-by step instructions are intended for:

- self-administration (adults)
- administration by a caregiver or healthcare professional to adults, adolescents or children aged over 2 years (weighing at least 12 kg).

The instructions include the following main steps:

- 1) General Information
- 2a) Preparing the syringe for children and adolescents (2-17 years) weighing 65 kg or less
- 2b) Preparing the syringe and needle for injection (all patients)
- 3) Preparing the injection site
- 4) Injecting the solution
- 5) Disposal of the injection material

Step-by-Step Instructions for Injection

1) General Information

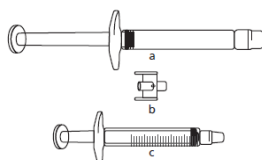
- Clean the work area (surface) to be used before beginning the process.
- Wash your hands with soap and water.
- Open the tray by peeling back the seal.
- Remove the pre-filled syringe from the tray.
- Remove the cap from the end of the pre-filled syringe by unscrewing the cap.
- Put down the pre-filled 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 (see below):

- a) FIRAZYR pre-filled syringe (containing icatibant solution)
- b) Connector (adapter)
- c) 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).



If you are not sure which volume of solution to extract, ask your doctor, pharmacist or nurse

- 1) Remove the caps on each end of the connector.



Avoid touching the ends of the connector and syringe tips, to prevent contamination

- 2) Screw the connector onto the pre-filled syringe.
- 3) Attach the graduated syringe to the other end of the connector ensuring that both connections fit securely.



Transferring the icatibant solution to the graduated syringe:

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



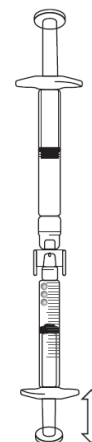
- 2) If the icatibant solution does not begin to transfer to the graduated syringe, pull slightly on the graduated syringe plunger until the icatibant solution starts to flow into the graduated syringe (see below image).



- 3) Continue to push on the pre-filled syringe plunger until the required injection volume (dose) is transferred to the graduated syringe. Refer to 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).



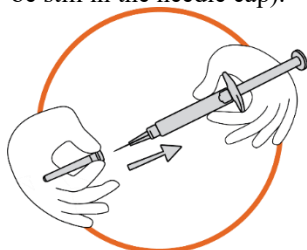
- Push the plunger of the graduated syringe so that any air is transferred back into the pre-filled syringe (this step may need to be repeated several times).

- Withdraw the required volume of icanibant solution.
- 4) Remove the pre-filled syringe and connector from the graduated syringe.
- 5) Discard the pre-filled syringe and connector into the sharps container.

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



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



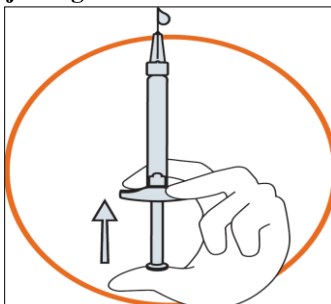
- Grip the syringe firmly. Carefully attach the needle to the syringe containing the colourless solution.
- Screw the syringe on the needle still fixed in the needle cap.
- Remove the needle from the needle cap by pulling the syringe. Do not pull up on the plunger.
- The syringe is now ready for injection.

3) Preparing the injection site



- Choose the injection site. The injection site should be a skin fold on your abdomen approximately 5-10 cm (2-4 inches) below your navel on either side. This area should be at least 5 cm (2 inches) away from any scars. Do not choose an area that is bruised, swollen, or painful.
- Clean the injection site with a rubbing alcohol pad 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 syringe between 45-90 degrees angle to skin with 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 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 fluid 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 container for throwing away waste that might hurt others if not handled properly.