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FIRAZYR Approved Patient Information Leaflet

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

Firazyr 30 mg icatibant solution for injection in pre-filled syringe

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.
- Do not share **FIRAZYR** with any other person
- Ask your doctor, pharmacist, or nurse if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

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What is in this leaflet

1. What FIRAZYR is and what it is used for

2. What you need to know before you take FIRAZYR

3. How to take FIRAZYR

4. Possible side effects

5. How to store FIRAZYR

6. Contents of the pack and other information

1. What FIRAZYR is and what it 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.

In HAE levels of a substance in your bloodstream called bradykinin are increased and this leads to symptoms like swelling, pain, nausea, and diarrhoea.

How FIRAZYR works

Firazyr blocks the activity of bradykinin and therefore ends the further progression of the symptoms.

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2. What you need to know before you use FIRAZYR

Do not use Firazyr

- If you are allergic to icatibant, or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor before taking **Firazyr**:

- if you are suffering from angina (reduced blood flow to the heart muscle)
- if you 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.

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- 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.

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.

Other medicines and Firazyr

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**.

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 before starting to use **Firazyr**.

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

Driving and using machines

Do not drive or use machines if you feel tired or dizzy as a result of your HAE attack or after using **Firazyr**.

Firazyr contains a small amount of sodium

The injection solution contains less than 1 mmol (23 milligrams) of sodium, so it is essentially ‘sodium-free’.

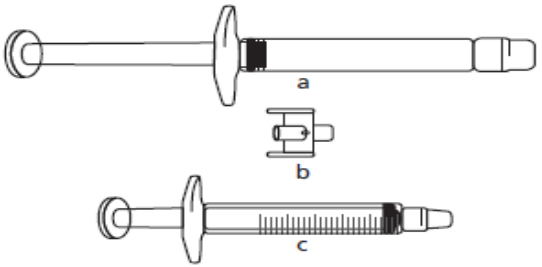
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3. How to use FIRAZYR

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

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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

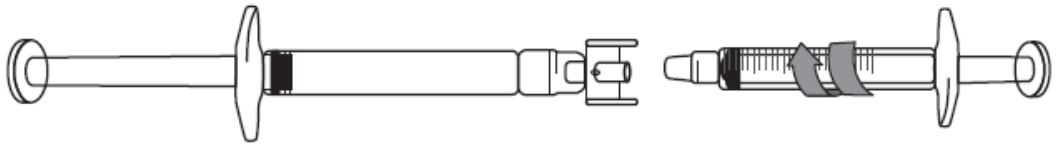
1) Remove the caps on each end of the connector.

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

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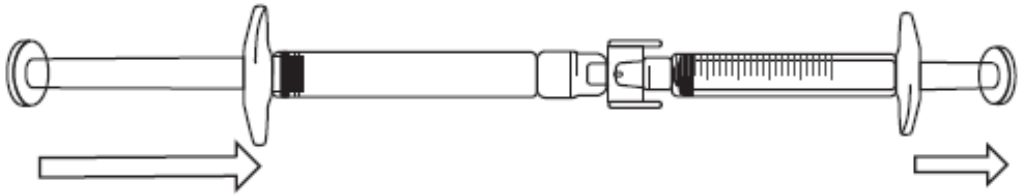
2) Screw the connector onto the pre-filled syringe.

3) Attach the graduated syringe to the other end of the connector ensuring that both connections fit securely.

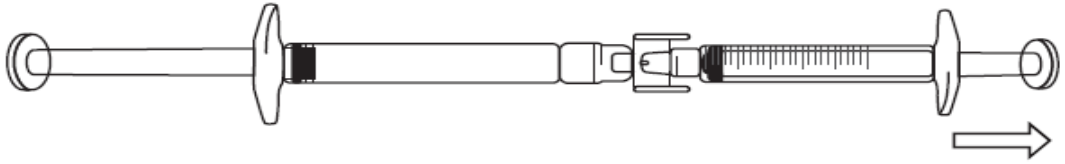


Transferring the icatibant solution to the graduated syringe:

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).

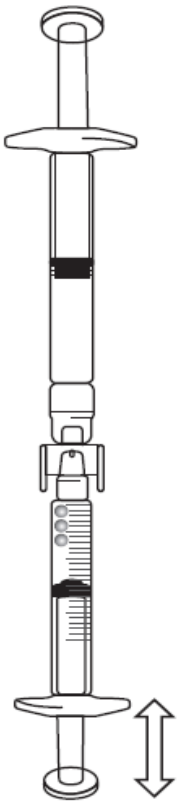


3) Continue to push on the pre-filled syringe plunger until the required injection volume (dose) is transferred to the graduated syringe. Refer to table 1 for dosage information.

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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).

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- Withdraw the required volume of icatibant 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).



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- 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.

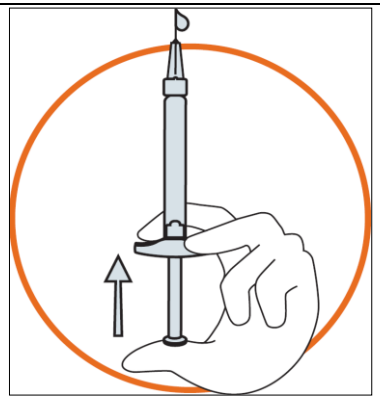
3) Preparing the injection site



- 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

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- 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.

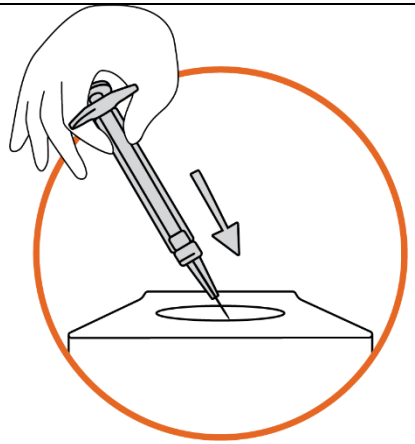


- Hold syringe between 45-90 degrees angle to skin with needle facing the skin.
- Keeping the syringe in one hand, use your other hand to gently hold a fold of skin between your thumb and fingers at the previously disinfected injection site.

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- 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.

If you use more Firazyr than you should

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Tell your doctor or pharmacist right away if you have taken more **Firazyr** than recommended.

If you forget to take Firazyr

Do not take a double dose to make up for a forgotten dose. Take your next dose at your regular time.

If you stop taking Firazyr

Do not stop taking **Firazyr** before talking to your doctor**.**

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

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4. Possible side effects

This medicine 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):

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Hives (urticaria)

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

If you get any side effects talk to your doctor. This includes any possible side effects not listed in this leaflet.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects you can help provide more information on the safety of this medicine.

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5. How to store FIRAZYR

Keep this medicine out of the sight and reach 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.

Do not store above 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.

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.

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6. Contents of the pack and other information

What Firazyr contains

The active substance is icatibant. Each pre-filled syringe contains 30 milligrams of icatibant (as acetate). The other ingredients are sodium chloride, acetic acid glacial, sodium hydroxide and water for injection.

What Firazyr looks like and contents of the pack

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 or as a multipack containing three pre-filled syringes with three needles.

Not all pack sizes may be marketed.

REGISTRATION NUMBER

550464

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