
Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about FIRAZYR.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines, including FIRAZYR have risks and benefits. Your doctor has weighed the risks of you having FIRAZYR against the benefits they expect it will have for you.

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

Keep this leaflet.

You may need to read it again.

What FIRAZYR is used for

FIRAZYR is used for treating the symptoms of an acute attack of hereditary angioedema (HAE).

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

How it works

FIRAZYR blocks the activity of bradykinin and therefore, helps reduce the symptoms of an HAE attack.

Before you use FIRAZYR

When you must not be given it

Do not use FIRAZYR if you have an allergy (hypersensitivity) to icatibant, or any of the other ingredients listed at the end of this leaflet.

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, skin rash, itching or hives.

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.

If you are pregnant or plan on becoming pregnant, discuss this with your doctor before starting to use FIRAZYR.

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

Do not give FIRAZYR to a child under 18 years.

The safety and effectiveness of FIRAZYR in children under 18 years have not been established.

Do not use FIRAZYR after the expiry date printed on the pack.

Do not use FIRAZYR if the packaging is torn or shows signs of tampering.

Do not use FIRAZYR if there are any visible signs of deterioration, for example if the solution is cloudy, if it has floating particles, or if the solution is not colourless.

If you are not sure whether you should use FIRAZYR, talk to your doctor or pharmacist.

Before you are given it

Consult your doctor before using FIRAZYR if you are suffering from angina (reduced blood flow to the heart muscle).

Inform 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.

Consult your doctor before using FIRAZYR if you have recently suffered a stroke.

Tell your doctor if you have allergies to:

- Any other medicines
- Any other substances, such as foods, preservatives or dyes.

Tell your doctor if you are pregnant or intend to become pregnant.

Your doctor will discuss the possible risks and benefits of using FIRAZYR during pregnancy.

Tell your doctor if you are breast-feeding. You should not breast-feed for 12 hours after you have received FIRAZYR.

It is not known whether FIRAZYR passes into your breast milk.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop. FIRAZYR can interact with other medicines e.g. ACE inhibitors (as previously discussed).

Food and drink have no effect on the action of FIRAZYR.

How FIRAZYR is used

Injections are usually administered by healthcare professionals. If you wish to inject FIRAZYR yourself and the doctor agrees it is appropriate (e.g. if you have a lot of HAE attacks or if you live far from a hospital or doctor), you will be trained on how to give yourself an injection.

The following information is for patients who have been trained to inject themselves:

As HAE attacks can often be serious, it is best to contact your doctor or hospital when you experience an attack.

If the HAE attack involves your face, lips, throat, or voice box, or if you have any difficulty breathing, you should always contact your doctor or hospital.

If your HAE attack has not shown signs of improvement within 2 hours of the injection of FIRAZYR; or if the attack spreads to your face, lips, throat, or voice box, or you develop any difficulty breathing, you should contact your doctor or hospital immediately.

It is possible to have further injections of FIRAZYR if you do not have relief from the HAE symptoms following the first injection; however, this should be done by your doctor or in hospital (see below) - or following the advice of your doctor.

FIRAZYR comes in a ready-to-use syringe. A needle is packed separately which you need to attach before use.

FIRAZYR is intended for subcutaneous injection (under the skin). FIRAZYR is injected into the fatty tissue under the skin in the abdomen (tummy).

Each syringe should only be used once.

Please see step-by-step instructions for injecting FIRAZYR at the end of this leaflet.

How much and when it is given

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

The recommended dose of FIRAZYR is one injection (30 mg in 3 mL) given subcutaneously (under the skin) as soon as the symptoms of an attack of HAE (for example increased skin swelling, particularly affecting the face and neck, or increasing tummy pain) become troubling.

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).

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

After using FIRAZYR

Things you must do

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

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

If you use too much (Overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at your nearest hospital if you think that an overdose has happened. 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.

Things to be careful of

Do not drive or operate any machinery if you feel tired or dizzy as a result of your HAE attack or after using FIRAZYR.

FIRAZYR has minor to moderate influence on the ability to drive and operate machinery.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well after using FIRAZYR.

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. The reaction may include burning sensations, reddening of the skin (erythema), pain, swelling, feeling of warmth, and itching (pruritus). These effects are usually mild and clear up by themselves without the need for any additional treatment.

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

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

- 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

These are the more common side effects of FIRAZYR. Mostly, these are mild and short-lived.

Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Do not be alarmed by this list of possible side effects as all medicines can cause side effects. You may not experience any of them.

Storing FIRAZYR

Keep FIRAZYR out of the reach and sight of children.

- Keep FIRAZYR in the original pack until it is time for it to be used.
- Keep it below 25°C. Do not freeze FIRAZYR.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product description

What it 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.

Ingredients

Active ingredient:

Icatibant acetate (equivalent to 30 mg of icatibant) in 3 mL solution for injection in each pre-filled syringe.

Other ingredients:

- Sodium chloride
- Acetic acid - glacial
- Sodium hydroxide
- Water for injections.

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

FIRAZYR does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Name and address of Sponsor and supplier

Shire Australia Pty Limited
Level 6
123 Epping Road,
North Ryde
NSW 2113
Australia
Freecall: 1800 012 612

AUST R number 160313

Date of preparation: November 2012

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Step-by-step instructions for injecting FIRAZYR

Step 1. Preparing your dose of FIRAZYR

- Wash your hands with soap and water
- You will need the following items:
 - Your FIRAZYR carton that includes 1 single-use FIRAZYR pre-filled syringe and 1 needle
 - An alcohol wipe
 - The medicine inside your FIRAZYR pre-filled syringe should be clear and colourless. Do not use your FIRAZYR pre-filled syringe if the solution contains particles, is cloudy, or an unusual colour.

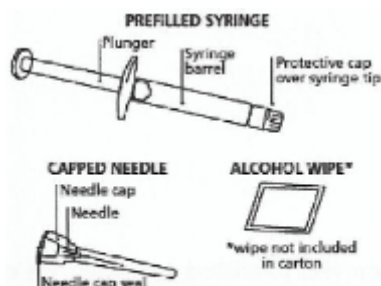


Figure A

Step 2. Remove pre-filled syringe and needle from the carton.

Step 3. Remove the seal from the needle cap. (the needle should remain inside the protective needle cap until ready to use). See Figure B.



Figure B

Step 4. Hold the syringe firmly. Carefully attach the needle to the pre-filled syringe containing the colourless FIRAZYR solution. See Figure C.

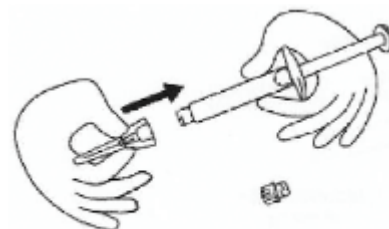


Figure C

Step 5. Firmly screw the needle on the pre-filled syringe. Be careful not to remove the needle from the needle cap. See Figure D.

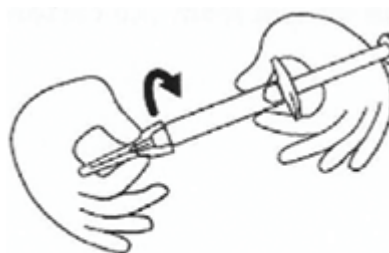


Figure D

Preparing the Injection Site

Step 6. Choose the injection site. The injection site should be a fold of skin on your stomach, about 5 to 10 cm below your belly button on either side. See Figure E.

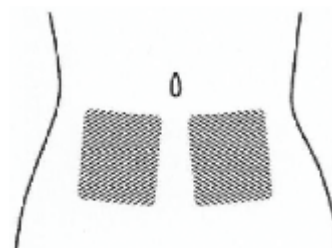


Figure E

The area you choose for injection should be at least 5 cm away from any scars. Do not choose an area that is bruised, swollen, or painful.

Step 7. Clean your FIRAZYR injection area with an alcohol wipe and allow it to dry. See Figure F.

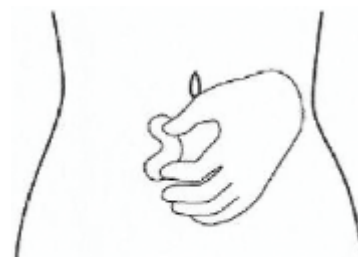


Figure F

Step 8. Remove the needle from the needle cap by holding the needle cap and carefully pulling the syringe. Do not pull on the plunger. See Figure G.



Figure G

Step 9. Hold the FIRAZYR syringe in one hand, between your fingers and thumb. See Figure H.

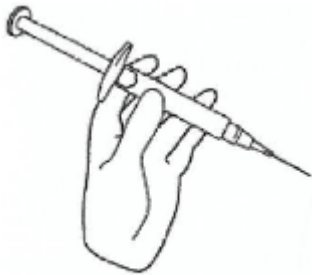


Figure H

Step 10. Use your other hand to gently pinch the fold of skin you cleaned with the alcohol wipe between your thumb and fingers for your injections. See Figure I.



Figure I

Step 11. Hold the syringe between a 45 to 90 degree angle to your skin with the needle facing the fold of skin you are holding. See Figure J.

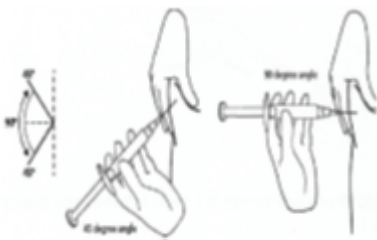


Figure J

Step 12. Hold the fold of the skin. Bring the syringe to the skin and quickly insert the needle into the skin fold. See Figure K.



Figure K

Step 13. Push the plunger, at the top of the syringe, over at least 30 seconds until no FIRAZYR is in the syringe. See Figure L.

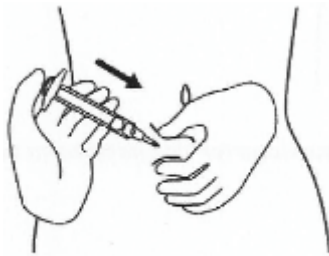


Figure L

Step 14. Release the skin fold and gently pull the needle out. See Figure M.

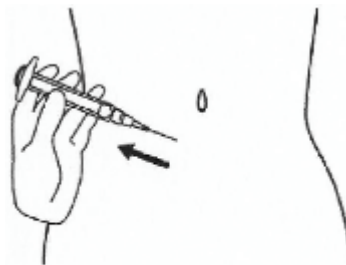


Figure M

Step 15. Place the used syringe with the needle attached in a sharps container which is made of hard materials and is sealable (such as biohazard container). Seal the container and throw it away the right way. There may be state and local laws about the right way to throw away used syringes and needles. Ask your healthcare providers or pharmacist how to throw away used syringes and needles. See Figure N.



Figure N