

PACKAGE LEAFLET: INFORMATION FOR THE USER

Firazyr 30 mg solution for injection pre-filled syringe Icatibant

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.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Firazyr is and what it is used for
2. What you need to know before you use Firazyr
3. How to use 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 adult patients. 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.

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).

Warning and precautions

Talk to your doctor before taking Firazyr:

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

In addition:

- You must be trained on subcutaneous (under the skin) injection technique before you self-inject 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-administered injection of Firazyr, you should seek medical advice regarding additional injections of Firazyr. Up to 2 additional injections may be given within 24 hours.

Children and adolescents

Firazyr is not recommended for use in children and adolescents under 18 years of age because it has not yet been studied in this age group.

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.

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'.

3. 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 the attack of hereditary angioedema. Your healthcare provider will teach you and your caregiver how to safely inject Firazyr by following the instructions in the Package Leaflet.

When and how often should you use Firazyr?

- Your doctor has determined the exact dose of Firazyr and will tell you how often it should be used. The recommended dose of Firazyr is one injection (3 ml, 30 mg) applied subcutaneously (under the skin) as soon as you notice the attack of hereditary angioedema (for example increased skin swelling, particularly affecting the face and neck, or increasing tummy pain).

If you experience no relief of symptoms after 6 hours, you should seek medical advice regarding additional injections of Firazyr. 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.

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 instruction is intended for self-administration only.

The instructions include the following main steps:

- 1) General Important Information
- 2) Preparing the syringe and needle for injection
- 3) Preparing the injection site
- 4) Injecting the solution
- 5) Disposal of the injection material

Step-by-Step Instructions for Injection

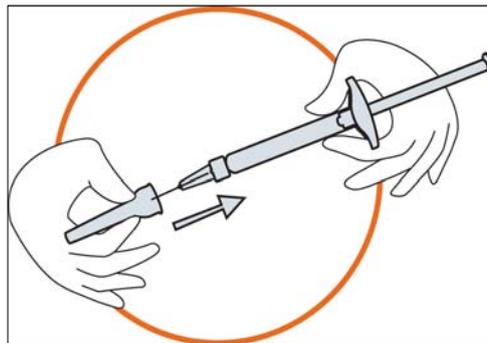
1) General Important Information

- Wash your hands with soap and water before beginning the process.
- Open the blister by peeling back the seal.
- Remove the pre-filled syringe from the blister 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.

2) Preparing the syringe and needle for injection

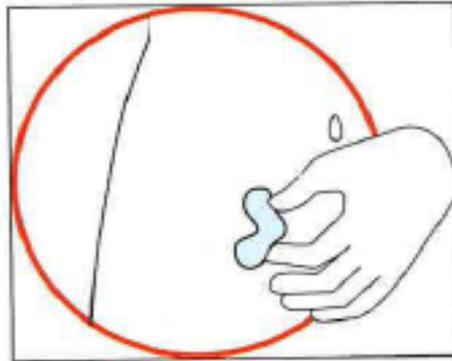


- Remove the needle cap from the blister.
- Remove the seal from the needle cap (the needle should be still in the needle cap).



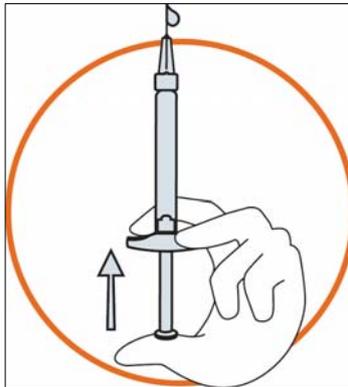
- Grip the syringe firmly. Carefully attach the needle to the pre-filled syringe containing the colourless solution.
- Screw the pre-filled syringe on the needle still fixed in the needle cap.
- Remove the needle from the needle cap by pulling the syringe. Do not pull up on the plunger.
- The syringe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



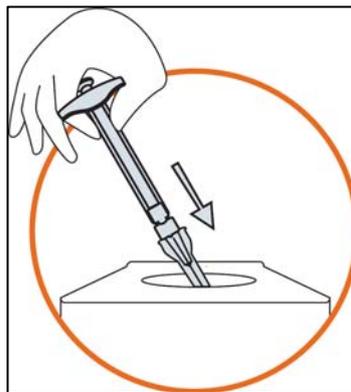
- Hold the syringe in one hand between two fingers with your thumb at the bottom of the plunger.
- Make sure that there is no air bubble in the syringe by pressing the plunger until the first drop appears on the tip of the needle.

4) Injecting the Solution (continued)



- 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.

4. Possible side effects

Like all medicines, 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.

The very common side effects (may affect more than 1 in 10 people) are:

Additional injection site reactions (pressure sensation, bruising, reduced sensation and/or numbness, raised itchy skin rash and warmth).

The common side effects (may affect up to 1 in 10 people) are:

Feeling sick

Headache

Dizziness

Fever

Itching

Rash

Skin redness

Abnormal liver function test

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. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to United Kingdom Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

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 waste water or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

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.

Marketing Authorisation Holder

Shire Orphan Therapies GmbH
Friedrichstrasse 149
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Manufacturer

Shire Human Genetic Therapies AB
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Other sources of information

Detailed information on this medicine is available on the European Medicines Agency website: <http://www.ema.europa.eu>. There are also links to other websites about rare diseases and treatments.