

*For adults with hereditary angioedema (HAE)
facing the possibility of unexpected attacks...*

Be prepared with FIRAZYR

**FIRAZYR® (icatibant injection) can be a key part
of your complete HAE treatment plan, even if
you are taking preventive therapy.**

Take on what's ahead.

Not a real patient.

Indication

FIRAZYR® (icatibant injection) is a medicine used to treat acute attacks of hereditary angioedema (HAE) in adults 18 years of age and older.

Important Safety Information

Laryngeal attacks can become life threatening. **If you have an HAE attack of the throat (laryngeal attack)**, inject FIRAZYR and then go to the nearest hospital emergency room right away.

Please see complete Important Safety Information on last page and [click here](#) for Full Prescribing Information, including Patient Information, which is also available at www.firazyr.com.

 **firazyr**[®]
(icatibant injection)



Welcome to FIRAZYR

FIRAZYR® (icatibant injection) is the first FDA-approved injection you give yourself under the skin (subcutaneously) to treat acute attacks of HAE—both in and out of the home—after you have been trained by a healthcare professional

This brochure is a guide to help you learn about:

- How FIRAZYR can be a key part of your HAE treatment plan
- How to treat HAE attacks with FIRAZYR
- Takeda Patient Support, which offers services to eligible patients who have been prescribed FIRAZYR

Important Safety Information

The most common side effects of FIRAZYR include:

- redness, bruising, swelling, warmth, burning, itching, irritation, hives, numbness, pressure, or pain at the injection site
- fever
- too much of an enzyme called transaminase in your blood
- dizziness
- nausea
- headache
- rash

These are not all of the possible side effects of FIRAZYR. Tell your healthcare provider if you have any side effect that bothers you or that does not go away. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

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Guidelines recommend that acute therapy be a part of every HAE treatment plan

Current guidelines recommend that people with HAE have an acute therapy as part of their treatment plan, so they are always prepared to treat if an unexpected attack occurs. **Guidelines also support exploring both preventive and acute therapy as part of a treatment plan.** People with HAE should be evaluated for long-term preventive treatment at every doctor's visit, or at least once a year.



People with HAE, including those taking a preventive therapy, are strongly encouraged to have enough acute treatment for 2 attacks, or at least 2 doses, on hand to be prepared if an attack happens



Guidelines also recommend that acute treatment of HAE attacks should be administered:

- As early as possible in an attack
- For all attacks, regardless of location, as soon as they are clearly recognized

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Treat HAE attacks both in and out of the home

FIRAZYR® (icatibant injection) is a portable acute therapy option for adults that can go wherever you go, so you are always prepared to treat an attack if needed

FIRAZYR is supplied as a 3-mL, prefilled, single-use syringe and is self-administered under the skin (subcutaneously) in the abdomen or stomach area.

- You may self-administer FIRAZYR after training by a healthcare professional

If your symptoms are not resolved or if symptoms occur again after your first dose of FIRAZYR, additional doses can be administered at least 6 hours apart (no more than 3 doses in any 24-hour period).

FIRAZYR does not need refrigeration or special handling

- Store between 36°F to 77°F (2°C to 25°C)
- Do not freeze
- Keep FIRAZYR in the original carton until you are ready to use it
- No mixing needed



Important Safety Information

Tell your healthcare provider if you have any other medical conditions, if you are breastfeeding or plan to breastfeed, or if you are pregnant or planning to become pregnant. FIRAZYR has not been evaluated in pregnant or nursing women. You and your

5 healthcare provider will decide if FIRAZYR is right for you.



Not a real patient.

Proven treatment that's ready if an unexpected attack occurs

FIRAZYR® (icatibant injection) can be used to treat all types of acute HAE attacks, including skin (cutaneous), stomach (abdominal), and throat (laryngeal).

In the pivotal trial (Trial 1), the median time to 50% reduction in symptoms of cutaneous or abdominal attacks was 2.0 hours for those treated with FIRAZYR vs 19.8 hours for those given placebo



In Trial 1, the median time to almost complete symptom relief was 8.0 hours vs 36.0 hours for FIRAZYR and placebo, respectively

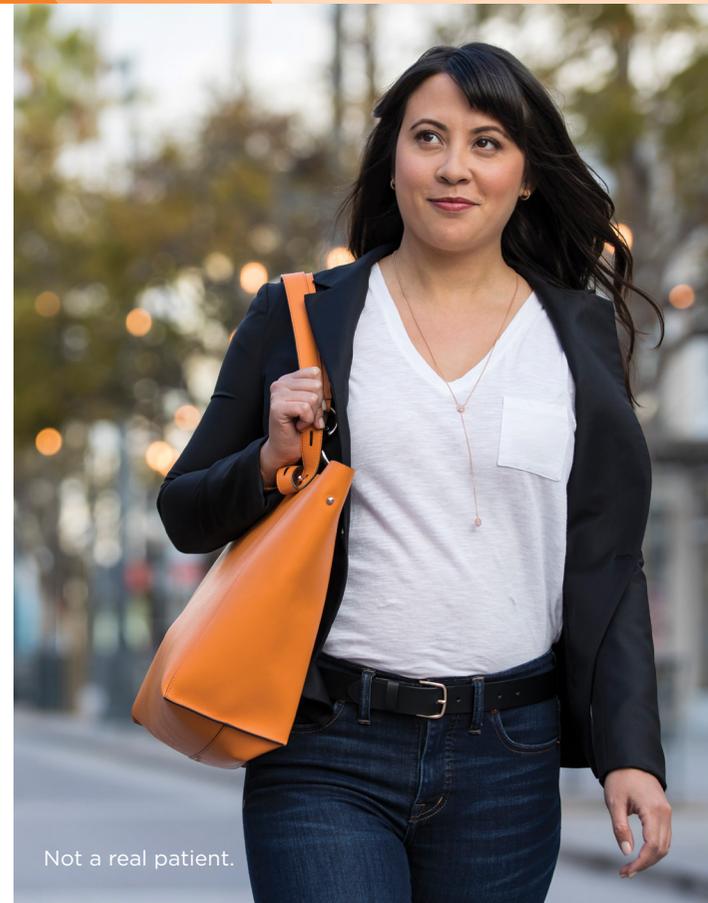


Across 3 controlled clinical trials, median time to 50% reduction from baseline symptoms ranged from 2.0 to 2.3 hours with FIRAZYR



In clinical trials, 9 out of 10 attacks were treated with a single dose of FIRAZYR

In controlled studies:
FIRAZYR was used to treat acute HAE attacks of the throat in 60 people. Symptom reduction was similar to results seen for skin and abdominal attacks. It is important to know that laryngeal (throat) attacks can become life-threatening. If you have an HAE attack involving the throat, inject FIRAZYR as directed and then go to the nearest hospital emergency room right away.



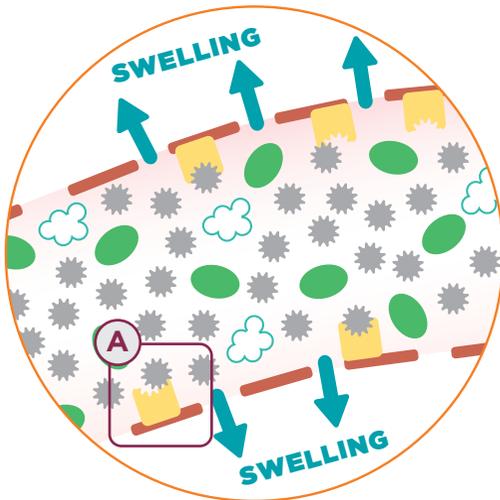
Not a real patient.

“ I felt the beginnings of an HAE attack and, thankfully, I had FIRAZYR in my bag and treated immediately. I'm proud that by treating the attacks quickly, my symptoms subsided. ”
—A real HAE patient

How does FIRAZYR work?

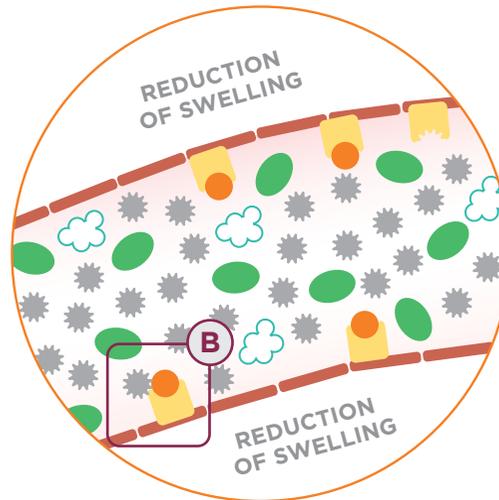
Most people with HAE either don't have enough proteins in the kallikrein-kinin system or the proteins do not work as they should, including C1 esterase inhibitor (C1-INH) and plasma kallikrein. This triggers the release of bradykinin. Increased bradykinin levels cause blood vessels to release fluid, resulting in the localized swelling and pain of an HAE attack.

Untreated person with HAE during an attack



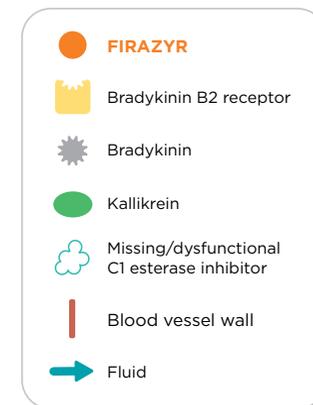
A Bradykinin binds to B2 receptors

Person with HAE after treatment with FIRAZYR



B FIRAZYR blocks bradykinin from binding to B2 receptors

FIRAZYR works by blocking bradykinin from binding to B2 receptors, which reduces the activity of bradykinin and thereby treats the symptoms of an acute HAE attack.



Important Safety Information

If your symptoms continue or come back, you may repeat your FIRAZYR injection at least 6 hours apart. Do not use more than 3 doses of FIRAZYR in a 24-hour period.

Please see complete Important Safety Information on last page and [click here](#) for Full Prescribing Information, including Patient Information, which is also available at www.firazyr.com.

Recognizing the symptoms of an HAE attack

HAE can cause attacks of swelling in any part of the body, but the most common locations include the skin (eg, face, hands, feet, genitals), abdomen, and throat.



Skin, or cutaneous

- Swelling of the skin usually affects the hands, feet, face, or genitals
- Can be temporarily disfiguring and disabling and get in the way of everyday activities
- May be accompanied by redness, but the area usually doesn't itch



Stomach, or abdomen

- Can cause mild to severe pain
- May be accompanied by vomiting and/or diarrhea
- Some people required bed rest for 24 to 50 hours due to their untreated abdominal attacks^a

^aIn a survey of 23 people with HAE.



Throat, or larynx

- Causes swelling in the throat, also called a laryngeal attack
- Swelling in the throat can interfere with breathing, creating a potentially life-threatening situation
- May cause other symptoms, such as voice changes and difficulty swallowing

Before an attack, some people with HAE experience early warning signs, also called prodromal symptoms, such as tingling, rash, fatigue, or nausea.

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Step-by-step instructions for injecting FIRAZYR

Getting started



You will need the following supplies:

- **Your FIRAZYR® (icatibant injection) carton**, which includes 1 single-use, prefilled syringe, and 1 needle
- **An alcohol wipe** (not included in carton)

IMPORTANT: The medicine inside your FIRAZYR prefilled syringe should be clear and colorless. Do not use your FIRAZYR prefilled syringe if the solution contains particles, is cloudy, or has an unusual color.

REMEMBER: Wash your hands with soap and water before handling any of the items needed for your injection, **and always handle supplies carefully to avoid contamination.**

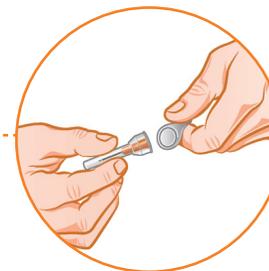
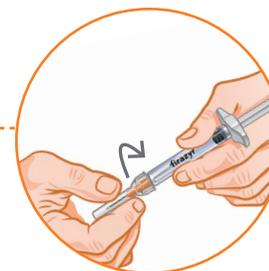
Important Safety Information

- Tiredness, drowsiness, and dizziness have been reported following the use of FIRAZYR. If this occurs, do not drive a car, use machinery,
- 9** or do anything that needs you to be alert.



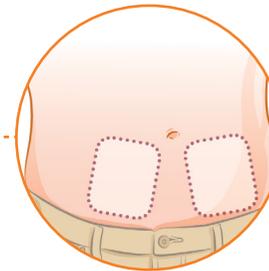
Preparing your dose

- 1 Remove the prefilled syringe and needle from the carton.
- 2 Twist the needle cap lid to break the seal (the needle should remain inside the protective needle cap until ready to use).
- 3 Remove the protective cap from the end of the prefilled syringe by unscrewing the cap. Hold the syringe firmly. Carefully attach the needle to the prefilled syringe containing the colorless FIRAZYR solution. Firmly screw the needle on the prefilled syringe.
 - Be careful not to remove the needle from the needle cap



Preparing the injection site

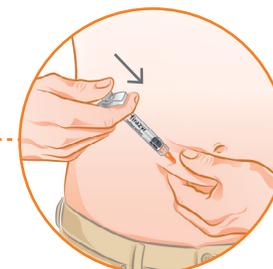
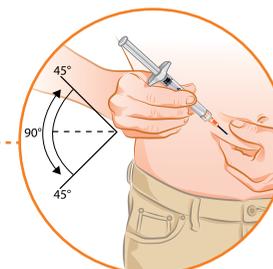
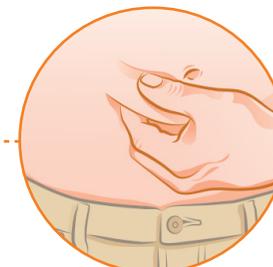
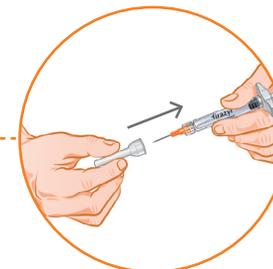
- 1 The injection site should be a skin fold on your stomach, about 2 to 4 inches (5 to 10 cm) below your belly button on either side, and should first be cleaned with an alcohol wipe and then allowed to dry.
 - The area you choose for injection should be at least 2 inches (5 cm) away from any scars. Do not choose an area that is bruised, swollen, or painful



Please see complete Important Safety Information on last page and [click here](#) for Full Prescribing Information, including Patient Information, which is also available

Injecting FIRAZYR

- 1** Remove the needle from the needle cap by holding the needle cap and carefully pulling the syringe. Hold the FIRAZYR® (icatibant injection) prefilled syringe in 1 hand, between your fingers and thumb.
 - Do not pull up on the plunger
- 2** Use your other hand to gently pinch the skin fold you cleaned between your thumb and fingers for your injection.
- 3** Hold the syringe between a 45- to 90-degree angle to your skin with the needle facing the skin fold you are holding.
- 4** While you are still holding the skin fold, bring the syringe to the skin and quickly insert the needle into the skin fold.
- 5** Push the plunger, at the top of the syringe, over at least 30 seconds until no FIRAZYR is in the syringe.
- 6** Once the syringe is empty, release the skin fold and gently pull the needle out.



Disposing of your used FIRAZYR prefilled syringe

- 1 Place your used syringe, with the needle attached, in an FDA-cleared sharps disposal container right away after use. Do not throw away (dispose of) loose needles and syringes in your household trash.

If you do not have an FDA-cleared sharps disposal container, you may use a household container that is:

- made of a heavy-duty plastic,
- can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
- upright and stable during use,
- leak-resistant, and
- properly labeled to warn of hazardous waste inside the container.

When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and syringes. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>.

Do not dispose of your sharps disposal container in your household trash unless your community guidelines permit this. **Do not** recycle your used sharps disposal container.



“I was a little apprehensive about self-injecting at first, but my doctor trained me how to do it step by step. He also went over the instructions that come in the package. He then explained that, in clinical trials, the majority of patients experienced injection-site reactions, and he emphasized the importance of going to the nearest emergency room right away if I have an attack of the throat.”

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—A real HAE patient



Not a real patient.

Common questions about FIRAZYR

What are the possible side effects of FIRAZYR?

The most common side effects of FIRAZYR® (icatibant injection) include redness, bruising, swelling, warmth, burning, itching, irritation, hives, numbness, pressure, or pain at the injection site; fever; too much of an enzyme called transaminase in your blood; dizziness; nausea; headache; and rash.

When should I take FIRAZYR?

FIRAZYR should be self-administered as soon as you recognize the symptoms of an HAE attack.

Can I give the injection myself?

You or your caregiver can administer FIRAZYR after receiving training from a healthcare professional. Takeda Patient Support offers injection training support. At your doctor's request, a specially trained nurse will take you step by step through the FIRAZYR injection process.

Can I use FIRAZYR for all of my attacks?

Guidelines recommend that you administer your acute treatment as early as possible in an attack and for all attacks, regardless of location, as soon as they are clearly recognized. Laryngeal attacks can become life threatening. If you have an attack in your throat (laryngeal attack), inject FIRAZYR and then go to the nearest hospital emergency room right away.

Can I take other medications with this product?

No studies have been conducted examining the interaction of FIRAZYR with other medications. Because FIRAZYR blocks bradykinin, it may affect how angiotensin-converting-enzyme (ACE) inhibitors work. You should let your doctor know about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements, and if you are taking an ACE inhibitor.

What else should I tell my doctor before taking FIRAZYR?

Tell your doctor if you have any other medical conditions, if you are breastfeeding or plan to breastfeed, or if you are pregnant or planning to become pregnant. FIRAZYR has not been evaluated in pregnant or nursing women. You and your healthcare provider will decide if FIRAZYR is right for you.

**Get the latest information,
resources, and tools at
www.firazyr.com/firazyr-resources**

Supporting patients with HAE for over 16 years

Takeda Patient Support offers tailored support for FIRAZYR® (icatibant injection). We understand that living with HAE looks different for everyone. Our long-term commitment to the HAE community allows us to better understand and meet your needs.

Our support specialists are here to address your questions and help get you the resources you need. Some of the resources we offer include:



- 🕒 **Enrolling** you in the **Takeda Patient Support Co-Pay Assistance Program**, if you qualify*
- 🕒 **Working** with your specialty pharmacy to **help you receive FIRAZYR**
- 🕒 **Arranging** for **in-home injection training** from a specially trained nurse
- 🕒 **Navigating** the **health insurance** process, along with help accessing financial insurance. Eligible patients can have their co-pays covered at 100%, up to the program maximum*
- 🕒 **Directing** you to **community support resources and education**

**To learn more about Takeda Patient Support
visit www.takedapatientssupport.com.**

You can also call 1-866-888-0660 Monday through Friday,
8:30 AM to 8 PM ET.



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