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.



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
- The personalized OnePath® product support services offered 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
- too much of an enzyme called transaminase in your blood
 - transaminase in
- dizziness

- nauseaheadache
- rash

• fever

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 <u>www.fda.gov/medwatch</u>, or call 1-800-FDA-1088.

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

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 healthcare provider will decide if FIRAZYR is right for you.





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



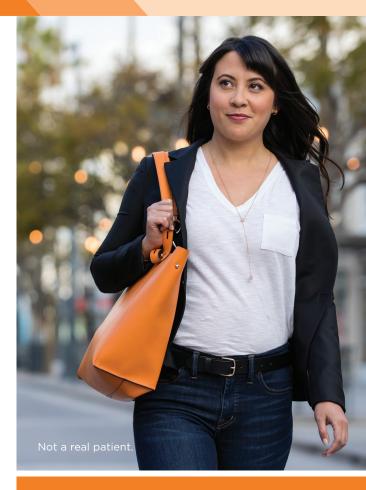
Across 3 controlled clinical trials, median time to 50% reduction from baseline symptoms ranged from 2.0 to 2.3 hours with FIRAZYR



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.

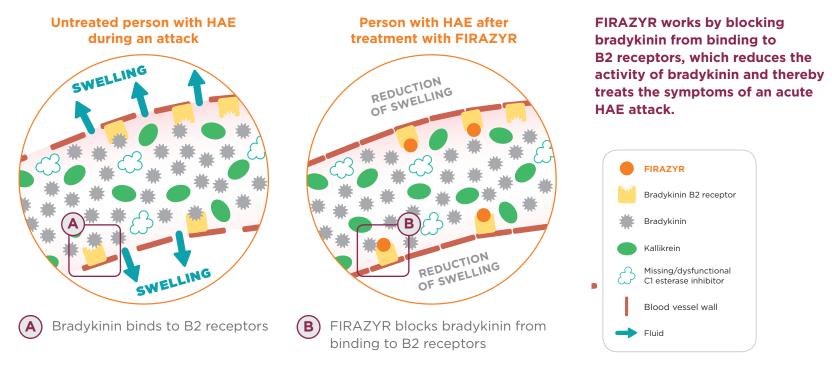


I felt the beginnings of an HAE attack and, thankfully, I had FIRAZYR in my bag and treated immediately. I'm proud that by treating the attacks quickly, my symptoms subsided.

-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.



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.

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.



- Causes swelling in the throat, also called a laryngeal attack
- Swelling in the throat can interfere with breathing, creating a potentially lifethreatening 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.

Important Safety Information

Tiredness, drowsiness, and dizziness have been reported following the use of FIRAZYR[®] (icatibant injection). If this occurs, do not drive a car, use machinery, or do anything that needs you to be alert.

For eligible patients, FIRAZYR offers access to OnePath® product support services

People who have been prescribed FIRAZYR and have enrolled in OnePath will be connected with a dedicated Patient Support Manager (PSM) who works with them to help ensure they get access to their medication, in addition to providing other services.

With your FIRAZYR treatment, OnePath provides you with:



A dedicated PSM to connect you with important information and resources about FIRAZYR and other Takeda HAE products that are part of your treatment plan



Help facilitating an insurance benefits investigation, and explaining insurance coverage and financial assistance options (if applicable)



In-home injection training and support for you and your caregiver(s) at no cost



Educational resources and the OnePath Mobile App for you and your caregiver(s) at no cost



For questions about OnePath, call

1-866-888-0660

OnePath is available Monday through Friday, from 8:30 AM to 8:00 PM ET.

OnePath also offers the following injection supplies:

- Sharps Recovery System[™] container to mail back used syringes and needles for proper disposal
- Pack of Point-Lok[®] needle caps for covering the needle after injecting FIRAZYR when you don't have access to your sharps container

Sharps Recovery System and Point-Lok are either trademarks or registered trademarks of their respective owners.

I carry FIRAZYR with me, whether I'm at home or traveling. That way, the very moment I start to notice swelling, even if it's in the middle of the night, I can treat.

-A real HAE patient

Not a real patient.

Additional resources and programs for you

The Takeda speaker programs offer educational events for you and your loved ones to learn more about living with HAE and treatment with the portfolio of HAE products from Takeda

The types of programs available to you include product programs presented by a healthcare professional and, when available, a patient ambassador will be featured.

Your OnePath PSM can tell you about any upcoming events in your area.



You can also connect with other people living with HAE by reaching out to the US Hereditary Angioedema Association (HAEA) by calling 1-866-798-5598 or emailing mentors@haea.org.

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. OnePath® offers injection training support. At your doctor's request, a specially trained nurse will take you step by step through the FIRAZYR injection process. You can watch an injection training video online at **www.firazyr.com/injectionvideo**.

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?

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

Please <u>click here</u> for Full Prescribing Information, including Patient Information, which is also available at www.firazyr.com.



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