

Takeda's commitment to FIRAZYR

What you and your patients can
expect from the patent expiration
and Takeda's continued support
of the HAE community



Indication

FIRAZYR® (icatibant injection) is indicated for the treatment of acute attacks of hereditary angioedema (HAE) in adults 18 years of age and older.

Important Safety Information

Warnings and precautions: Given the potential for airway obstruction during acute laryngeal HAE attacks, patients should be advised to seek medical attention in an appropriate healthcare facility immediately in addition to treatment with FIRAZYR.

Please see the complete Important Safety Information on page 9 and [click here](#) for Full Prescribing Information, including Patient Information, which is also available at www.firazyr.com.



Takeda remains committed to you and your HAE patients



The patent for FIRAZYR® (icatibant injection) expires on July 15, 2019.

After this date, generic versions of icatibant may become available. Brand name FIRAZYR will continue to be available.

At Takeda, our ongoing commitment leading up to the patent expiration for FIRAZYR includes the following:

- Continued manufacturing and availability of FIRAZYR
- Product support services through OnePath® for your eligible FIRAZYR patients
- Resources to help make patients aware of the patent expiration for FIRAZYR

Contact the Takeda representative in your area with questions you may have about treatment with FIRAZYR.

- Beginning in July 2019, information will be available for you, your office, and your patients at www.firazyr.com/hcp/takedas-commitment

OnePath will continue to provide product support services to your enrolled patients by offering access to a dedicated Patient Support Manager (PSM) who can:

- Facilitate an insurance benefits investigation
- Coordinate injection training, if applicable
- Provide information about financial assistance

Patients can only receive OnePath product support services for the prescribed Takeda products they are taking. State restrictions may apply for OnePath co-pay assistance.



For questions about OnePath, call

1-866-888-0660

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

Important Safety Information

Adverse reactions: The most commonly reported adverse reactions were injection-site reactions, which occurred in almost all patients (97%) in clinical trials. These injection-site reactions included bruising, hematoma, burning, erythema, hypoesthesia, irritation, numbness, edema, pain, pressure sensation, pruritus, swelling, urticaria, and warmth.

Other common adverse reactions included pyrexia (4%), transaminase increase (4%), and dizziness (3%), as well as rash, nausea, and headache.

Please see the complete Important Safety Information on page 9 and [click here](#) for Full Prescribing Information, including Patient Information, which is also available at www.firazyr.com.



Helping your patients who want to receive FIRAZYR

If you and your patients decide to include brand name FIRAZYR as part of their treatment plan, there are steps you can take to help:



Reach out to your patients to inform them of the patent expiration and discuss their options for continuing acute treatment



Fill out an updated FIRAZYR OnePath Start Form (see details on page 5 for filling out the updated Start Form and completing a new prescription)



Once you and your patients have made the treatment decision to continue using brand name FIRAZYR, OnePath will continue to support your patients in gaining access to their prescribed Takeda treatment



Suggest that your patients contact their specialty pharmacy to indicate they wish to receive brand name FIRAZYR. Patients can ask the pharmacy to make a note of this in their file. This may ensure that FIRAZYR is filled or that your patient's specialty pharmacy contacts your office before switching them to a generic icatibant

Important Safety Information

Drug interactions: FIRAZYR is a bradykinin B2 receptor antagonist and thereby has the potential to have a pharmacodynamic interaction with ACE inhibitors where FIRAZYR may attenuate the antihypertensive effect of ACE inhibitors. Clinical trials to date have excluded subjects taking ACE inhibitors.

How to help ensure your patients receive brand name FIRAZYR



Add specific instructions required by your state (eg, “brand medically necessary”) on the FIRAZYR OnePath Start Form

- Include this information on the FIRAZYR prescription you write for your patient’s specialty pharmacy
- For current patients, you may need to fill out a new FIRAZYR OnePath Start Form
- The rules for dispensing branded products vary by state so ensure that your prescriptions include your state’s specific regulations. For a list of state-by-state regulations for prescribing brand name products, go to [**www.firazyr.com/hcp/takedas-commitment**](http://www.firazyr.com/hcp/takedas-commitment)



Inform patients that you can send a letter of medical necessity to their insurance provider, if needed. A sample letter of medical necessity is available at [**www.firazyr.com/hcp/takedas-commitment**](http://www.firazyr.com/hcp/takedas-commitment) that you can refer to when writing a letter for your patients

If you have questions about treatment with FIRAZYR, please contact your Takeda representative.

Please see the complete Important Safety Information on page 9 and [click here](#) for Full Prescribing Information, including Patient

5 Information, which is also available at [**www.firazyr.com**](http://www.firazyr.com).



Questions you may have about the patent expiration for FIRAZYR

Q What is the difference between a generic icatibant and brand name FIRAZYR® (icatibant injection)?

According to the FDA, generic drugs are intended to be the same as an existing approved brand name drug in dosage form, safety, strength, route of administration, quality, and performance characteristics.¹ Brand name FIRAZYR has been manufactured and produced by Shire, now part of Takeda, since its FDA approval in 2011.² Generic icatibant may be manufactured by companies other than Takeda.

Q How can I help ensure brand name FIRAZYR will be dispensed if that is the treatment plan my patients and I choose?

If you would like your patients to receive brand name FIRAZYR, you will have to specifically indicate it on the FIRAZYR OnePath Start Form in accordance with the language your state requires.

Q How will my patients recognize brand name FIRAZYR?

Tell your patients to examine the package and syringe of their prescription to be sure they received brand name FIRAZYR. Differentiating features you can point out for them include:

- FIRAZYR brand name in orange letters on the box
- Black FIRAZYR logo on the syringe
- The Shire logo on the box (Shire is now a part of Takeda)



Questions you may have about the patent expiration for FIRAZYR (cont'd)

Q Will my patients still have access to OnePath product support services with a generic icatibant?

OnePath can only provide product support for the Takeda HAE products a patient is taking. If your patient switches from brand name FIRAZYR to a product not made by Takeda, they will no longer be eligible for OnePath product support services.

Q How will patients be made aware of the patent expiration for FIRAZYR?

We will be reaching out to FIRAZYR patients through email, mail, and telephone. However, your Takeda representative can provide you with the “What to Expect” patient guide in a prestamped envelope for you to share directly with your FIRAZYR patients as appropriate.

Q What is the cost difference for my patients between a generic icatibant and brand name FIRAZYR?

Coverage will vary by insurance carrier, insurance plan, and state.

Please see the complete Important Safety Information on page 9 and [click here](#) for Full Prescribing Information, including Patient

7 Information, which is also available at www.firazyr.com.



Questions you may have about the patent expiration for FIRAZYR (cont'd)

Q Will co-pay assistance continue to be available for patients taking FIRAZYR® (icatibant injection)?

Patients who are enrolled in the OnePath Co-Pay Assistance Program may have 100% of their insurance co-pay for FIRAZYR covered, up to the program maximum.

Patients 18 years of age and older with commercial insurance may be eligible for the OnePath Co-Pay Assistance Program.* There are no financial requirements or waiting periods to participate in this program. Actual co-pays may vary by insurance carrier and plan, and program availability may vary by state.

Your patients can reach out to OnePath to help them evaluate what their potential out-of-pocket cost may be for brand name FIRAZYR and for information about the co-pay program. They can contact OnePath at 1-866-888-0660 to learn more.

***IMPORTANT NOTE:** The OnePath Co-Pay Assistance Program (the Program) is not valid for prescriptions eligible to be reimbursed, in whole or in part, by Medicaid, Medicare (including Medicare Part D), Tricare, Medigap, VA, DoD, or other federal or state programs (including any medical or state prescription drug assistance programs). No claim for reimbursement of the out-of-pocket expense amount covered by the Program shall be submitted to any third party payer, whether public or private. The Program cannot be combined with any other rebate/coupon, free trial, or similar offer. Copayment assistance under the Program is not transferable. The Program only applies in the United States, including Puerto Rico and other U.S. territories, and does not apply where prohibited by law, taxed, or restricted. This does not constitute health insurance. Void where use is prohibited by your insurance provider. If your insurance situation changes you must notify the Program immediately at 1-866-888-0660. Coverage of certain administration charges does not apply for patients residing in Massachusetts, Michigan, Minnesota, Rhode Island, and Vermont. Takeda reserves the right to rescind, revoke, or amend the Program at any time without notice. Additional program restrictions and eligibility requirements apply.

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Adverse reactions: The most commonly reported adverse reactions were injection-site reactions, which occurred in almost all patients (97%) in clinical trials. These injection-site reactions included bruising, hematoma, burning, erythema, hypoesthesia, irritation, numbness, edema, pain, pressure sensation, pruritus, swelling, urticaria, and warmth.

Other common adverse reactions included pyrexia (4%), transaminase increase (4%), and dizziness (3%), as well as rash, nausea, and headache.

Drug interactions: FIRAZYR is a bradykinin B2 receptor antagonist and thereby has the potential to have a pharmacodynamic interaction with ACE inhibitors where FIRAZYR may attenuate the antihypertensive effect of ACE inhibitors. Clinical trials to date have excluded subjects taking ACE inhibitors.

Use in specific populations: Clinical studies of FIRAZYR included a limited number of subjects aged 65 and over. Elderly patients are likely to have increased systemic exposure. Reported clinical experience has not identified differences in efficacy and safety between elderly and younger patients.

Safety and effectiveness in patients below 18 years of age have not been established.

Please [click here](http://www.firazyr.com) for Full Prescribing Information, which is also available at www.firazyr.com.

Takeda's continued support for FIRAZYR patients

Our goal is to ensure that you and your office have the information you need to help your patients make decisions about their treatment plan.



Reach out to the Takeda representative in your area with any questions you may have about brand name FIRAZYR.



Visit www.firazyr.com/hcp/takedas-commitment for more information and to download additional resources, such as a sample letter of medical necessity.

Contact OnePath if you have any questions about product support services for your OnePath enrolled FIRAZYR patients.

- The OnePath team is available at 1-866-888-0660, Monday through Friday, 8:30 AM to 8:00 PM ET
- OnePath can only provide product support services for the Takeda product your patients are prescribed



References: 1. US Food and Drug Administration. Generic drug facts. <https://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/genericdrugs/ucm167991.htm>. Accessed April 25, 2019. 2. FIRAZYR® (icatibant injection) Prescribing Information. Shire.



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