# Takeda's commitment to FIRAZYR

What to expect from the patent expiration for FIRAZYR and Takeda's continued support of the HAE community

#### **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 the complete Important Safety Information on page 7 and <u>click here</u> for Full Prescribing Information, including Patient Information, which is also available at www.firazyr.com.



# What does the patent expiration for FIRAZYR mean?

The patent for FIRAZYR® (icatibant injection) expires on July 15, 2019. After this date, generic options of icatibant may become available. Brand name FIRAZYR will continue to be available.

### Takeda remains committed to you and the HAE community



At Takeda, we understand the role that FIRAZYR has played in treating hereditary angioedema (HAE) attacks since 2011. That's why we are committed to offering ongoing support for people prescribed FIRAZYR

- Continued manufacturing and availability of FIRAZYR
- OnePath® will continue to provide product support services to eligible patients

It is important to note that OnePath can only provide product support services for the Takeda HAE product you are prescribed. Contact your doctor or your OnePath Patient Support Manager (PSM) if you have questions about access to treatment with FIRAZYR. You'll find answers to questions you may have about the patent expiration for FIRAZYR on the following pages.

#### **Important Safety Information**

The most common side effects of FIRAZYR include:

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

dizziness

rash

fever

These are not all of the possible side effects of FIRAZYR.

Please see the complete Important Safety Information on page 7 and click here for Full 2 Prescribing Information, including Patient Information, which is also available at www.firazyr.com.

# How to continue receiving treatment with brand name FIRAZYR

You can take an active role in advocating for yourself and the HAE treatment you wish to receive.

### Here are some steps you can take if you and your doctor choose brand name FIRAZYR:



**Ask your doctor** to complete a new OnePath Start Form and write your prescription for brand name FIRAZYR to include any special instructions required by your state (eg, "dispense as written")

• The rules for dispensing branded products vary by state and your physician should be aware of what is needed on your prescription and OnePath Start Form



**Tell the pharmacist** at your specialty pharmacy that you want brand name FIRAZYR and ask them to put a note in your file. This may ensure that FIRAZYR is filled or that your specialty pharmacy contacts you or your doctor before switching you to generic icatibant



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

### Connect with the US Hereditary Angioedema Association (HAEA)

The HAEA is a patient advocacy organization serving HAE patients. If you have questions about HAE, support, and self-advocacy, they may be a helpful resource to connect with after talking to your doctor.



# Questions you may have about the patent expiration for FIRAZYR

# What does "brand name FIRAZYR" and "generic icatibant" mean?

FIRAZYR® (icatibant injection) is the registered name (also known as the "brand name") for the treatment that is manufactured by Takeda and was approved by the FDA in 2011. Icatibant is the active ingredient in FIRAZYR. Generic icatibant is a treatment that may become available after the patent for FIRAZYR expires and may be made by a number of different companies.

# O How is a generic icatibant different from brand name FIRAZYR?

Brand name FIRAZYR has been manufactured by Shire, now part of Takeda, since its FDA approval in 2011.

According to the FDA, generic drugs are intended to be the same as an existing approved brand name drug in the way that it works, the way it is taken, and the way it should be used. Generic icatibant may be manufactured by companies other than Takeda.

### Is it possible I will receive a generic icatibant when I refill my FIRAZYR prescription?

Yes. You may be switched to generic icatibant by your specialty pharmacy.

If you receive a generic icatibant, there are steps you can take to help receive brand name FIRAZYR moving forward if that is the treatment plan you and your doctor choose. See page 3 for more information. The most important step you can take if you receive generic icatibant and want to continue to receive brand name FIRAZYR is to let your doctor know.

We encourage you to reach out to your doctor to discuss your options for continuing acute treatment.

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

Will I still be able to receive OnePath support with a generic icatibant?

OnePath can only provide product support services for the Takeda HAE product you are prescribed. If you have questions about being switched to a generic icatibant or maintaining OnePath product support, you can reach out to your doctor to discuss your treatment plan.

How will I recognize brand name FIRAZYR?

When you receive your prescription, look for distinguishing features on the packaging and syringe. The box should include the FIRAZYR name in orange letters and a Shire logo (Shire is now a part of Takeda). The syringe should have a black FIRAZYR logo on it. If it does not, you have received a generic icatibant.



**Q** Does Takeda plan to continue producing FIRAZYR?

Yes, Takeda remains committed to people with HAE and to helping make FIRAZYR available for those who want to receive it.

Please see the complete Important Safety Information on page 7 and <u>click here</u> for Full Prescribing Information, including Patient Information, which is also available at www.firazyr.com.



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

# Will co-pay assistance still be available for FIRAZYR® (icatibant injection)?

The OnePath Co-Pay Assistance Program\* will continue to be available from Takeda for eligible patients to help reduce the out-of-pocket costs of your FIRAZYR prescription. State restrictions may apply.

Eligible patients with commercial insurance may have 100% of FIRAZYR co-pays covered, up to the program maximum.

# Q Am I eligible for co-pay assistance?

You may be eligible for the OnePath Co-Pay Assistance Program\* if you are a patient 18 years of age and older and have commercial insurance.

There are no financial requirements or waiting periods to participate in this program. Eligibility may differ depending on your insurance company, type of plan, and state of residence.

Your OnePath PSM can help you evaluate your eligibility for the OnePath Co-Pay Assistance Program and determine what your potential out-of-pocket costs may be for brand name FIRAZYR. **Contact OnePath at 1-866-888-0660 to learn more.** 

\*IMPORTANT NOTICE: 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.

#### 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.

The most common side effects of FIRAZYR include:

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

dizziness

headache

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

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.

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.

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 click here for Full Prescribing Information, including Patient Information, which is also available at www.firazyr.com.



# Takeda's continued support for those taking FIRAZYR

We are here to support you while you advocate for the HAE treatment you want.

 OnePath can only provide product support services for the Takeda HAE product you are prescribed.
 Co-pay assistance eligibility for brand name FIRAZYR may differ depending on your insurance company, type of plan, and state of residence





### Reach out to your OnePath Patient Support Manager (PSM)

for help with insurance questions, co-pay assistance information, and product support for FIRAZYR® (icatibant injection)

—OnePath is available at 1-866-888-0660, Monday through Friday, 8:30 AM to 8:00 PM ET



### Visit www.firazyr.com/takedas-commitment for more information

and to download helpful resources, such as a Discussion Guide, to help you have a conversation with your doctor about your treatment plan







