YOUR INFUSION EXPERIENCE

What to expect before, during, and after your infusion with Fabrazyme® (agalsidase beta)
Scheduling your Fabrazyme infusion

Infusions can be received in a hospital, infusion center, or a doctor’s office. You will need to contact the infusion site to schedule your first infusion and subsequent infusions. To better incorporate infusions into your life, you may be able to make a request regarding day and time of your infusion.

Proper planning

Your Fabrazyme infusion time may be approximately 4 to 5 hours or more when you first start treatment, depending on the infusion site’s policies. You should have a support person to provide transportation, as you will not know how you will feel following the infusion and you may be prescribed medications before or during your infusion that cause drowsiness.

If you safely tolerate the infusion, your doctor may reduce your infusion time. Clinical studies have shown that over time, some patients can reduce their infusion times to between 2 and 3 hours. Infusion times vary among patients. Talk with your doctor about what to expect for your infusion time.

Day of the infusion: What to expect

On the day of your scheduled infusion, you will arrive at the infusion site and check in to let them know who you are and that you are there for your infusion. After you have been taken to your infusion area, the nurse will perform an assessment. This assessment may include asking you how you are currently feeling, weighing you, and measuring your heart rate, blood pressure, and temperature. If you are not feeling well, the nurse may want to consult with your doctor prior to starting the infusion.

You may be given anti-fever medications (such as acetaminophen or ibuprofen) to help prevent reactions that your body may have to Fabrazyme. Infusion reactions still occurred in some people even after receiving anti-fever medications, antihistamines, and oral steroids. Some reactions were serious. These medications are typically referred to as “pre-treatment medications.”

Possible wait time

You may have to wait for the pharmacy to prepare your Fabrazyme once you arrive at the infusion area.

How Fabrazyme is delivered

Following the assessment, the nurse will start your IV, either through a vein in your arm (venous access) or through a port, if you have one. This is how Fabrazyme will get into your body during the infusion.

The infusion

Once your Fabrazyme arrives, the nurse will hang the bag and attach it to a pump with IV tubing that will attach to your infusion line. The pump will regulate the speed at which the Fabrazyme is delivered to you. The speed of the infusion may change based on the doctor’s orders, how you are feeling, and your vital signs. During the infusion, the area around the needle may feel cold as the Fabrazyme enters your body. A blanket may be useful to help keep you comfortable.

REMEMBER

Infusion reactions are common. If you experience any changes in how you are feeling, let the nurse know immediately.

If an infusion reaction occurs, slowing the infusion rate, stopping the infusion for a short time and/or giving more anti-fever and antihistamine medications and/or steroids may improve the symptoms. If severe infusion reactions happen, your healthcare professional should consider stopping the Fabrazyme infusion right away and should provide medical care for your condition. Severe reactions are generally managed by giving antihistamine medications, corticosteroids, fluids through the vein, and/or oxygen when needed.

You can experience an infusion-related reaction after your infusion as well. If you experience changes in how you feel, notify your doctor or seek medical attention.

Please see accompanying full Prescribing Information and Important Safety Information.
Indication and Usage

Fabrazyme® (agalsidase beta) is used to treat patients with Fabry disease. Fabrazyme lowers the amount of a substance called globotriaosylceramide (GL-3), which builds up in cells lining the blood vessels of the kidney and certain other cells.

The lowering of GL-3 suggests that Fabrazyme may improve how Fabry disease affects your body; however, a relationship of lower GL-3 to specific signs and symptoms of Fabry disease has not been proven.

Important Safety Information

Fabrazyme can cause serious side effects, including:

Severe Allergic Reactions (anaphylaxis): Life-threatening severe allergic (anaphylactic) reactions have been seen in patients during Fabrazyme infusions. Approximately 1% of patients who have received Fabrazyme either during a clinical study or after Fabrazyme was approved have experienced anaphylactic or severe allergic reactions during their infusion.

- These reactions have included: localized swelling of the face, mouth and throat, narrowing of breathing airways, low blood pressure, hives, difficulty swallowing, rash, trouble breathing, flushing, chest discomfort, itching and nasal congestion.
- People who have experienced these reactions have required treatment including heart/lung resuscitation, oxygen, fluids given through the vein, hospitalization, and have needed treatment with inhaled drugs called beta-adrenergic agonists to help open the breathing airways, antihistamines, epinephrine (also known as adrenalin), and a medication given through the vein called a corticosteroid (or steroid) which helps to decrease the body’s allergic reaction by decreasing inflammation.
- If you experience a severe allergic or anaphylactic reaction, your healthcare professional will immediately stop the infusion of Fabrazyme and provide you the necessary emergency medical treatment. Because of the possibility that severe allergic reactions may occur, appropriate medical support should be available during your Fabrazyme infusion.

Infusion-Associated Reactions: In clinical studies with Fabrazyme, 59% of patients experienced infusion-associated reactions during Fabrazyme administration, some of which were severe.

- For patients who have had reactions to their infusions, it is recommended that they be given anti-fever and antihistamine medications right before their next infusions. Infusion-associated reactions have happened in some patients even after taking these medications before their infusions.
- If an infusion-associated reaction occurs, slowing the infusion rate, stopping the infusion for a short time and/or giving more anti-fever and antihistamine medications and or steroids may improve the symptoms.
- If severe infusion-associated reactions happen, your healthcare professional should consider stopping the Fabrazyme infusion right away and should provide medical care for your condition. Severe reactions are generally managed by giving antihistamine medications, corticosteroids, fluids through the vein, and/or oxygen when needed. Because severe infusion-associated reactions may happen, medical treatment should be readily available during your Fabrazyme infusion.

Planning

- For your first infusion, you should plan to have someone transport you to and from the infusion site.
- You will be at the infusion site for several hours. Consider bringing a sweater or blanket, something to read or watch, snacks and beverages to make your time as comfortable as possible.
- You do not need to fast before the infusion.
- If you have questions about what you can or cannot bring to your infusion, call the site and ask before your infusion.

Some doctors include restrictions on food or drink during infusions, so ask your doctor or the infusion nurse if you have any restrictions or if you can eat and drink as you like.

Schedule conflicts

For future planning, if you know you are going to miss an infusion, let your nurse or infusion site know. Try to adjust your infusion prior to the conflict or reschedule as soon as possible. You should discuss any changes to your infusion schedule with your doctor prior to adjusting your appointments. Infusions do not have to be exactly two weeks apart. It is important to receive your infusions so you are not behind on them.

Your CareConnectPSS Case Manager can help if you need assistance finding a different infusion site.

Amanda and Cindy, Fabry patients
Important Safety Information, continued

Pre-existing Heart Problems: People with advanced Fabry disease may have heart problems, which may put them at a higher risk for severe complications from infusion-associated reactions. These patients should be watched closely during their infusion if the decision is made to give them Fabrazyme.

Immune Response and Continued Treatment After Allergic Reaction: In the clinical studies, a few patients developed IgE antibodies or a reaction to an allergy skin test specific to Fabrazyme. IgE antibodies are usually produced by the body's immune system during an allergic reaction. Your doctor should consider testing for IgE antibodies if you experience suspected allergic reactions. Providing Fabrazyme to patients who have experienced severe or serious allergic reactions to Fabrazyme should only be done after carefully considering the risks and benefits of continuing the treatment, and only under the direct supervision of a qualified healthcare professional and with appropriate medical support readily available.

Common and Other Possible Side Effects:

• Common side effects reported in 20% or more of Fabrazyme treated patients in clinical studies compared to placebo were upper respiratory tract infection, headache, cough, burning and/or tingling sensation, fatigue, dizziness, swelling in the legs, and rash.

• Serious and/or frequently occurring side effects (occurring in 5% or more of the patients) thought to be related to Fabrazyme in placebo-controlled and open-label clinical studies have included: chills, fever, feeling hot or cold, trouble breathing, nausea, flushing of the skin, headache, vomiting, burning and/or tingling sensation, fatigue, itching, pain in the hands and feet, high blood pressure, chest pain, throat tightness, abdominal pain, dizziness, rapid heart rate, nasal congestion, diarrhea, swelling in the legs, muscle pain, back pain, paleness of the skin, slow heart rate, hives, low blood pressure, face swelling, rash and sleepiness.

• Other serious side effects that were seen in the clinical studies included stroke, pain, lack of muscle coordination, slow or irregular heartbeat, stopping of the heartbeat, decreased blood pumped by the heart, dizziness, and kidney problems resulting in too much protein leaving the body in the urine (nephrotic syndrome). These side effects also occur as part of Fabry disease.

• Since Fabrazyme has been approved, there have been side effects that resulted in death that may or may not be related to the use of Fabrazyme. These included: the heart and/or lungs stop working (known as cardiorespiratory arrest, respiratory failure, and/or cardiac failure), life-threatening infection in the blood stream (known as sepsis), stroke, heart attack, kidney failure, and pneumonia. Some of these side effects were reported in Fabry disease patients with significant underlying disease.

The safety and effectiveness of Fabrazyme in patients younger than 8 years of age have not been studied.

Please see full Prescribing Information for Fabrazyme.

Sanofi Genzyme Offers Support

Your Sanofi Genzyme Patient Education Liaison can answer your questions about infusions and help explain the need for infusions to your work or school. Call 1-800-745-4447 (option 3) for more information.