Cerezyme®

(imiglucerase) for injection

Preparation and Administration

DOSAGE

Cerezyme is administered as an intravenous infusion over 1 to 2 hours

- The recommended dosage of Cerezyme is 2.5 units/kg three times a week to 60 units/kg once every two weeks administered intravenously.
- For patients weighing greater than 20 kg, infuse the diluted Cerezyme solution over 1 to 2 hours. For patients weighing 20 kg or less, infuse the diluted Cerezyme solution over 2 hours.
- Administer Cerezyme under the supervision of a healthcare provider knowledgeable in the management of hypersensitivity reactions including anaphylaxis.
- Titrate the dosage based on disease severity and therapeutic goals for the patient.
- If a severe hypersensitivity reaction occurs, discontinue Cerezyme treatment and initiate appropriate medical treatment. Consider the risks and benefits of readministering Cerezyme to individual patients following a severe reaction.
- For patients who experience mild to moderate hypersensitivity reactions to Cerezyme, consider reducing the rate of infusion, temporarily stopping the infusion and premedicate with antihistamines, antipyretics and/or corticosteroids. Monitor patients for the occurrence of new hypersensitivity reactions (see Warnings and Precautions).

Storage and Handling:

Cerezyme for injection is supplied as a white to off-white lyophilized powder in a single-dose vial: NDC 58468-4663-1

- Cerezyme vials should be stored refrigerated at 2°C to 8°C (36°F to 46°F)
- Cerezyme does not contain preservatives
- If the reconstituted Cerezyme vial is not used immediately, refrigerate at 36°F to 46°F (2°C to 8°C) or store at room temperature at 68°F to 77°F (20°C to 25°C) for up to 12 hours.
- Refrigerate the diluted solution at 36°F to 46°F (2°C to 8°C) for up to 24 hours.

Indication:

Cerezyme® (imiglucerase) for injection is indicated for the treatment of non-central nervous system (CNS) manifestations of Type 1 or Type 3 Gaucher disease in adult and pediatric patients.

Important Safety Information

WARNING: HYPERSENSITIVITY REACTIONS INCLUDING ANAPHYLAXIS

Patients treated with enzyme replacement therapies have experienced life-threatening hypersensitivity reactions, including anaphylaxis. Anaphylaxis has occurred during the early course of enzyme replacement therapy and after extended duration of therapy.

Initiate Cerezyme in a healthcare setting with appropriate medical monitoring and support measures, including access to cardiopulmonary resuscitation equipment. If a severe hypersensitivity reaction (e.g., anaphylaxis) occurs, discontinue Cerezyme and immediately initiate appropriate medical treatment, including use of epinephrine. Inform patients of the symptoms of life-threatening hypersensitivity reactions, including anaphylaxis, and to seek immediate medical care should symptoms occur.

Please see Important Safety Information throughout and full Prescribing Information, including Boxed WARNING.

RECOMMENDED SUPPLIES

Preparation

- 1-mL, 10-mL, 20-mL, and 60-mL syringes
- 18-gauge to 20-gauge needles
- Supplies for proper aseptic preparation (e.g., isopropyl alcohol)
- Infusion bag or syringe for infusion (size dependent on product and dose)

Administration

- Compatible intravenous infusion set
- In-line low protein-binding 0.2 µm filter
- Appropriate medical support measures (e.g., Anaphylactic Kit per physician orders, as needed)

GENERAL PRACTICES

- Store vials in refrigerator and monitor refrigerator temperature at least once daily
- Suggest not to reconstitute the product until patient is present and venous access is obtained
- Use aseptic technique during preparation
- Determine the number of vials based on weight and dose
- Determine the total volume
- Plan resources for preparation

PREPARATION TECHNIQUE PRACTICES

1. Determine the number of Cerezyme vials to be reconstituted based on the individual patient's dosage regimen and remove vial(s) from the refrigerator.
2. Reconstitute each vial of Cerezyme by slowly injecting 10.2 mL of Sterile Water for Injection, down the inside wall of each vial.
3. Roll and tilt the vial to allow the powder to dissolve completely. Visually inspect the reconstituted solution for particulate matter and discoloration. Discard if opaque particles or discoloration are observed. After reconstitution, each vial will yield Cerezyme at a concentration of 40 units/mL.
4. Withdraw the required volume of Cerezyme from the vial(s).
5. Dilute the Cerezyme solution for infusion promptly with 0.9% Sodium Chloride Injection to a final volume that is calculated based on prescribed dose. For Cerezyme administered at a dose of 60 units/kg, use the following final volumes:
   - For patients weighing between 1.5 kg and less than 6 kg, dilute Cerezyme to a final volume of 12 mL in a syringe for infusion.
   - For patients weighing between 6 kg and less than 13 kg, dilute Cerezyme to a final volume of 26 mL in a syringe for infusion.
   - For patients weighing between 13 kg and less than or equal to 20 kg, dilute Cerezyme to a final volume of 100 mL in an infusion bag.
   - For patients weighing greater than 20 kg and less than or equal to 100 kg, dilute Cerezyme to a final volume of 200 mL in an infusion bag.
   - For patients weighing greater than 100 kg, dilute Cerezyme to a final volume of 400 mL in an infusion bag.
6. If Cerezyme is prescribed at a dose lower than 60 units/kg, dilute the required total units of reconstituted solution (at a concentration of 40 units/mL) with 0.9% Sodium Chloride Injection to a final concentration between 6 units/mL and 30 units/mL inclusive. If the determined dose translates into a total volume of 26 mL or less, administer using a syringe for infusion via a syringe pump.
7. For accuracy of dilution, if less than 2 mL of reconstituted Cerezyme (40 units/mL) is needed for the preparation of the determined dose, prepare a larger final volume for infusion initially maintaining the final concentration of the diluted solution between 6 units/mL to 30 units/mL. Subsequently, discard the excess volume and administer only the volume of Cerezyme solution corresponding to the prescribed dose.
8. Gently invert the syringe for infusion or the infusion bag to mix the solution. Throughout preparation, avoid vigorous shaking, agitation and foaming.

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ADMINISTRATION

- Visually inspect the diluted solution prior to administration of the final product for particulate matter and discoloration. Slight flocculation of protein particles (described as thin translucent fibers) may occur after dilution and does not affect the quality of the product.
- Administer Cerezyme as an intravenous infusion with a 0.2 micron in-line low protein-binding filter
- Prior to administration of Cerezyme® (imiglucerase) for injection:
  - — Obtain the patient's baseline vital signs, including blood pressure, temperature, pulse, and respirations
  - — Obtain IV access; antecubital, wrist, or hand veins may be used. If the patient has a port, access port as per protocol.
  - — Draw the required blood work, if any ordered
  - — Connect the 0.2 micron in-line filter to the IV administration set. Flush or prime IV tubing and filter with 0.9% sodium chloride.
  - — Connect IV administration set to the Cerezyme infusion bag or syringe for infusion
  - — Prime the IV administration set with Cerezyme, being careful not to allow excess fluid to drip from the end of the set
- After the IV administration line has been primed, connect to the patient's IV access or port
- Begin the infusion at a rate that will result in an administration length over 1 to 2 hours as instructed in the Prescribing Information and the Physician's orders. See Table 1 in PI for maximum infusion rates.
- Monitor the IV site for any infiltration
- Monitor vital signs at 15 minutes, 60 minutes, and at the completion of the infusion or as directed by the Physician
- Do not infuse Cerezyme in the same intravenous line with other products
- Upon completion of Cerezyme, discard infusion bag or infusion syringe per institutional procedures
- Flush the infusion line with 0.9% sodium chloride to ensure the entire dose of Cerezyme has been administered. Use the last infusion rate tolerated by the patient.
- Do not "IV push" the normal saline flush through
- After infusion, the line is flushed to deliver all of the medication that is in the infusion line; this can be done with control at the same rate as the drug

If an allergic reaction to Cerezyme occurs, stop the infusion and manage accordingly. Contact the attending Physician immediately.

Contact Sanofi Medical Information at 1-800-745-4447, Option 2.

Important Safety Information (cont'd)

Warnings and Precautions:

Hypersensitivity Reactions Including Anaphylaxis: See Boxed WARNING.

Patients with antibody to imiglucerase have a higher risk of hypersensitivity reactions. Consider periodic monitoring during the first year of treatment for IgG antibody formation.

Consider risks and benefits of readministering Cerezyme to individual patients following a severe reaction. Consider reducing the rate of infusion, pretreat with antihistamines and/or corticosteroids, and monitor patients for new signs and symptoms of a severe hypersensitivity reaction.

Please see Important Safety Information throughout and full Prescribing Information, including Boxed WARNING.

A LONG-STANDING COMMITMENT TO THE GAUCHER COMMUNITY

For more than 30 years, Sanofi has been committed to helping address the needs of people living with Gaucher disease and those who care for them.

As the pioneer of Gaucher disease treatment, Sanofi brings unmatched years of research, development, and patient data to its Gaucher disease program. Sanofi will continue to serve this community for years to come and remains committed to advancing Gaucher disease care through treatment options that address the range of patients' disease statuses and lifestyle demands.

Important Safety Information (cont'd)

Infusion-Associated Reactions:

Infusion associated reactions (IARs) have been observed in patients treated with Cerezyme. If an IAR occurs, decreasing the infusion rate, temporarily stopping the infusion and/or administering antihistamines and/or antipyretics may ameliorate the symptoms. Closely monitor patients who have experienced IARs when re-administering Cerezyme.

Adverse Reactions:

- Adverse reactions reported in adults and pediatric patients include back pain, chills, dizziness, fatigue, headache, hypersensitivity reactions, nausea, pyrexia, and vomiting.

www.cerezyme.com

sanofi

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Monday - Friday 8:00 am-6:00 pm

Please see accompanying Full Prescribing Information, including Boxed WARNING.

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