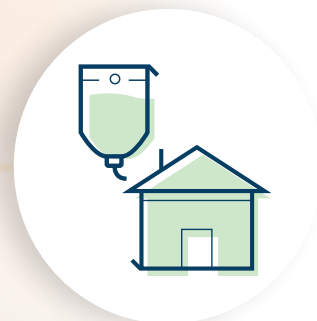




Xenpozyme[®]
(olipudase alfa-rpcp)
For Injection, 20 mg

HOME INFUSION WITH XENPOZYME

A GUIDE FOR TRANSITIONING TO HOME INFUSION



INDICATION

XENPOZYME[®] (olipudase alfa-rpcp) is indicated for treatment of non-central nervous system manifestations of acid sphingomyelinase deficiency (ASMD) in adult and pediatric patients.

IMPORTANT SAFETY INFORMATION

WARNING: SEVERE ALLERGIC REACTIONS

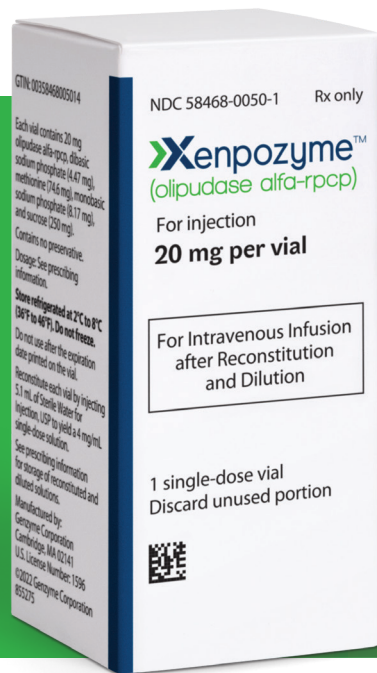
Allergic Reactions Including Anaphylaxis

Allergic reactions, including severe reactions that may be serious or life-threatening (known as anaphylaxis), have occurred during and after XENPOZYME treatment. Tell your healthcare provider right away if you develop any reactions, and seek immediate medical care if severe reactions occur. If a severe allergic reaction occurs, your doctor may decide to discontinue XENPOZYME immediately and provide appropriate medical care. Appropriate medical support measures may be administered, and you may require close observation during and after XENPOZYME administration.

Please see [Important Safety Information](#) and full [Prescribing Information](#) for complete details, including Boxed WARNING.

WHAT IS XENPOZYME?

XENPOZYME IS THE FIRST AND ONLY DISEASE-SPECIFIC TREATMENT FOR NON-CENTRAL NERVOUS SYSTEM (NON-CNS) MANIFESTATIONS OF ACID SPHINGOMYELINASE DEFICIENCY (ASMD)



WHEN TRANSITIONING TO HOME INFUSION, IT IS IMPORTANT TO KNOW WHAT IS AHEAD SO YOU CAN BE PREPARED.

LEARN MORE AT XENPOZYME.COM

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Allergic Reactions (Including Anaphylaxis) and Infusion-Associated Reactions (IARs)

See Boxed WARNING for more information. Your doctor may decide to give you antihistamine, anti-fever, and/or steroid medications before your infusions. Signs of allergic reactions and infusion-associated reactions (IARs) included hives, itchy skin, skin redness, rash, swelling underneath the skin, tender bumps under the skin, and localized swelling, as well as headache, vomiting, nausea, fever, and diarrhea.

Reactions may occur during and/or after the infusion. Tell your healthcare provider right away if you experience any reactions. Your healthcare provider may slow or stop the infusion or may lower the next dose.

Please see [Important Safety Information](#) and full [Prescribing Information](#) for complete details, including **Boxed WARNING**.

IS HOME INFUSION AN OPTION?

- You or your child has completed the dose escalation phase of treatment, during which your doctor started you or your child on a low dose of XENPOZYME and gradually escalated the dose over at least 14 weeks (for adults) or at least 16 weeks (for children) to the target maintenance dose of 3 mg/kg.
- If you or your child is tolerating infusions well on the maintenance dose, your doctor may decide that treatment can be given at home under the supervision of a nurse.

HOW TO GET STARTED WITH HOME INFUSION



➤ STEP 1: GET HELP FINDING A HOME INFUSION AGENCY

Your **CareConnect Personalized Support Services Case Manager** and/or **Patient Education Liaison (PEL)** can assist in finding a home health agency that is capable of providing home infusion.



➤ STEP 2: RECEIVE AND STORE SUPPLIES

Unlike infusions in a clinical setting, you will be responsible for receiving, storing, and possibly ordering XENPOZYME and supplies needed for your home infusions. Before your first home infusion occurs, you will be mailed a large box of medical supplies and a smaller box with XENPOZYME that will be necessary for your infusions.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (CONTINUED)

Elevated Transaminases Levels

XENPOZYME may be associated with elevated liver enzymes (known as transaminases) within 24 to 48 hours after infusion. Your doctor should check your liver enzyme levels with a blood test:

- within one month before starting XENPOZYME;
- within 72 hours before any infusion during the dose escalation phase, or before your next scheduled XENPOZYME infusion if you missed a dose.

Based on the results of your blood tests, your doctor may make changes to your dose or infusion schedule. Upon reaching the recommended maintenance dose, your doctor may continue to monitor your liver enzyme levels.

Please see [Important Safety Information](#) and full [Prescribing Information](#) for complete details, including **Boxed WARNING**.

HOW IS RECEIVING INFUSIONS AT HOME DIFFERENT FROM RECEIVING INFUSIONS IN A CLINICAL SETTING?

Xenpozyme[®]
(olipudase alfa-rpcp)
For Injection, 20 mg

› HOW IT IS SIMILAR:

- XENPOZYME is still prescribed by your doctor.
- XENPOZYME is still administered under the supervision of a trained nurse.

› HOW IT IS DIFFERENT:

- XENPOZYME may be prepared by a pharmacy and shipped to your home OR your nurse may prepare it while they are at your home.
- XENPOZYME and infusion supplies will be received, stored, and possibly ordered by you, unlike the infusions you received at the hospital or infusion center.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (CONTINUED)

Risk to Unborn Babies

Starting or increasing the dose of XENPOZYME is not recommended in a pregnant female as it may cause harm (birth defects) to the developing baby. If you are pregnant or plan to become pregnant, tell your doctor right away.

If you are a female of reproductive potential, your doctor will verify your pregnancy status before you start treatment with XENPOZYME. You should use effective contraception during XENPOZYME treatment and for 14 days after your last dose if XENPOZYME is discontinued.

Please see [Important Safety Information](#) and full [Prescribing Information](#) for complete details, including **Boxed WARNING**.

HOW IMPORTANT IS IT TO ADHERE TO THE HOME INFUSION SCHEDULE?



IT IS VERY IMPORTANT TO FOLLOW YOUR INFUSION SCHEDULE

- In people with ASMD, the body is unable to make enough of the ASM enzyme; therefore, it is important to keep taking XENPOZYME every 2 weeks to continue to help reduce the buildup of sphingomyelin in the cells.
 - Contact your doctor for help in scheduling a time and day of the week that work best for you or your child to stay on track.
- **If you or your child misses 3 or more infusions in a row, returning to the dose escalation phase will be required before resuming the maintenance dose.**
 - You or your child might need to go back to the hospital or infusion center to receive infusions until you reach the maintenance dose again.
 - There may also be additional logistical delays related to missed doses. If you miss a scheduled dose, contact your doctor to discuss returning to your regular dosing schedule.

ASM=acid sphingomyelinase.

IMPORTANT SAFETY INFORMATION

ADVERSE REACTIONS

- Most frequently reported adverse drug reactions in adults (incidence $\geq 10\%$) were headache, cough, diarrhea, low blood pressure, and redness in the eye.
- Most frequently reported adverse drug reactions in pediatric patients (incidence $\geq 20\%$) were fever, cough, diarrhea, runny nose, abdominal pain, vomiting, headache, hives, nausea, rash, joint pain, itchy skin, fatigue, and sore throat.

Please see [Important Safety Information](#) and full [Prescribing Information](#) for complete details, including **Boxed WARNING**.

PREPARING FOR HOME INFUSION

IF YOUR DOCTOR GIVES YOU THE OPTION OF RECEIVING XENPOZYME AT HOME, HERE IS WHAT YOU NEED TO KNOW:

- **FIRST:** Your home environment must be able to accommodate the home infusion therapy by providing an appropriate space to receive the infusion and ample storage space for supplies.
 - Unlike infusions in a clinical setting, you will be responsible for receiving, storing, and possibly ordering XENPOZYME and supplies for your infusions.
- **SECOND:** Your doctor will decide the appropriate dose and discuss logistics with you:
 - You will be educated on treatment at home, the associated risks, and which medical personnel will administer the home infusion.
 - XENPOZYME at-home infusions must always be given under the supervision of a trained healthcare provider who will ensure that appropriate medical support measures, including cardiopulmonary resuscitation equipment, are readily available during XENPOZYME administration.

BEFORE YOUR FIRST HOME INFUSION, YOU WILL RECEIVE 2 BOXES IN THE MAIL:

- 1 A large box of medical supplies
- 2 A smaller box with XENPOZYME that will be necessary for your infusion

WHEN THE LARGE BOX OF MEDICAL SUPPLIES ARRIVES:

- **OPEN THE PACKAGE:** Look through the contents to see if there are any special storage instructions in the large box that you need to follow.
- **DO NOT SHAKE.**
- **MAKE SURE** nothing has been damaged or leaked in shipment.
- **CHECK** the contents against the shipping list to make sure you received the correct supplies.
- **STORE IN THE REFRIGERATOR:** Some of these supplies must be refrigerated between 2 °C/36 °F and 8 °C/46 °F.



IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Allergic Reactions (Including Anaphylaxis) and Infusion-Associated Reactions (IARs)

See Boxed WARNING for more information. Your doctor may decide to give you antihistamine, anti-fever, and/or steroid medications before your infusions. Signs of allergic reactions and infusion-associated reactions (IARs) included hives, itchy skin, skin redness, rash, swelling underneath the skin, tender bumps under the skin, and localized swelling, as well as headache, vomiting, nausea, fever, and diarrhea.

Reactions may occur during and/or after the infusion. Tell your healthcare provider right away if you experience any reactions. Your healthcare provider may slow or stop the infusion or may lower the next dose.

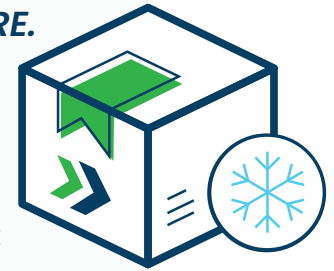
Please see [Important Safety Information](#) and full [Prescribing Information](#) for complete details, including **Boxed WARNING**.

PREPARING FOR HOME INFUSION

WHEN THE SMALLER BOX WITH XENPOZYME ARRIVES, IT MUST BE REFRIGERATED, NOT FROZEN, BETWEEN 2 °C/36 °F AND 8 °C/46 °F AND HANDLED WITH CARE.

YOU MUST:

- **RECEIVE MEDICATION SHIPMENT:** Be at home to receive the medication shipment, or make arrangements to have it delivered at a different time or to an alternate location (such as a neighbor's house).
- **STORE IN REFRIGERATOR:** Be sure you have enough space in your refrigerator for the amount of XENPOZYME that will be shipped.



STORAGE TIPS:

- Some people find it helpful to use a mini refrigerator just for XENPOZYME.
- Some people store the other supplies in drawers reserved for medical supplies, small drawer organizers, or in an over-the-door shoe rack.

WHAT ELSE MAY BE NEEDED?



Because your dosing is based on your weight, you may need to have a scale available for periodic weight checks per your nurse's orders or home health agency policies. Your dosing may change periodically if there are significant changes in your weight.



Your home environment must be able to accommodate the preparation and administration of infusions by providing an appropriate space to receive the infusions and ample storage space for supplies.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (CONTINUED)

Elevated Transaminases Levels

XENPOZYME may be associated with elevated liver enzymes (known as transaminases) within 24 to 48 hours after infusion. Your doctor should check your liver enzyme levels with a blood test:

- within one month before starting XENPOZYME;
- within 72 hours before any infusion during the dose escalation phase, or before your next scheduled XENPOZYME infusion if you missed a dose.

Based on the results of your blood tests, your doctor may make changes to your dose or infusion schedule. Upon reaching the recommended maintenance dose, your doctor may continue to monitor your liver enzyme levels.

Please see [Important Safety Information](#) and full [Prescribing Information](#) for complete details, including **Boxed WARNING**.

WHAT TO EXPECT ON THE DAY OF YOUR HOME INFUSION

Xenpozyme[®]
(olipudase alfa-rpcp)
For Injection, 20 mg

The first home infusion may take longer than those you received at the hospital or infusion center. The infusion nurse will check over your supplies, review your therapy orders, and have a discussion with you regarding your infusion process.

BEFORE YOUR INFUSION BEGINS, THE NURSE WILL:

- Give you pretreatment medication, if needed.
- Allow your XENPOZYME to **come to room temperature**.
- Perform a **clinical assessment**.
- Make sure they are able to **gain access to a vein** (or medication port, if you have one).

Once those steps are complete, **your nurse will prepare your medication** and perform any other necessary steps prior to infusion.

THE NURSE WILL REMAIN WITH YOU THROUGHOUT THE INFUSION and for an appropriate time after your infusion is completed.

IMPORTANT: During the infusion, always be sure to let the nurse know if you or your child experiences any changes in how you are feeling. These may be signs of a reaction.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (CONTINUED)

Risk to Unborn Babies

Starting or increasing the dose of XENPOZYME is not recommended in a pregnant female as it may cause harm (birth defects) to the developing baby. If you are pregnant or plan to become pregnant, tell your doctor right away.

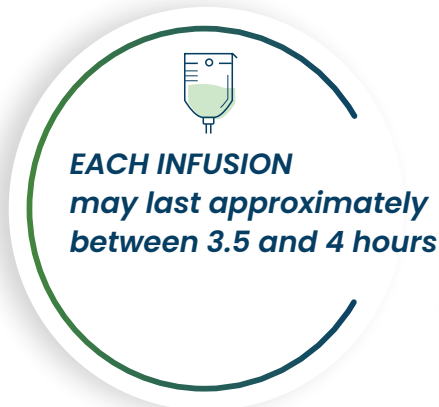
If you are a female of reproductive potential, your doctor will verify your pregnancy status before you start treatment with XENPOZYME. You should use effective contraception during XENPOZYME treatment and for 14 days after your last dose if XENPOZYME is discontinued.

Please see [Important Safety Information](#) and full [Prescribing Information](#) for complete details, including **Boxed WARNING**.

FOLLOW THESE STEPS TO ESTABLISH A ROUTINE FOR YOUR INFUSIONS:

Xenpozyme[®]
(olipudase alfa-rpcp)
For Injection, 20 mg

- Make sure you set aside enough time in your calendar for regular, biweekly infusions.
- On the day of your infusion, prepare a space in a room where you will feel comfortable.
- Allow additional time for preparation and post-infusion observation. Each infusion may last approximately between 3.5 and 4 hours.
- Establish a routine and plan some light activities you enjoy (e.g., reading a book or watching TV) to help pass the time.



IMPORTANT SAFETY INFORMATION

ADVERSE REACTIONS

- Most frequently reported adverse drug reactions in adults (incidence $\geq 10\%$) were headache, cough, diarrhea, low blood pressure, and redness in the eye.
- Most frequently reported adverse drug reactions in pediatric patients (incidence $\geq 20\%$) were fever, cough, diarrhea, runny nose, abdominal pain, vomiting, headache, hives, nausea, rash, joint pain, itchy skin, fatigue, and sore throat.

Please see [Important Safety Information](#) and full [Prescribing Information](#) for complete details, including **Boxed WARNING**.

WHAT TO LOOK OUT FOR DURING INFUSION

- **Hypersensitivity reactions:** In clinical trials, some adults and children experienced mild, moderate, or severe hypersensitivity reactions associated with the XENPOZYME infusion, such as hives, redness of the skin, or itchy skin.
- **Infusion-associated reactions (IARs):** Some adults and children experienced side effects in the clinical trials that may have been associated with the XENPOZYME infusion. Reactions may occur during and after the infusion.

If you or your child experiences hypersensitivity, IARs, or any other side effects, tell your doctor right away.

IMMEDIATELY SEEK URGENT MEDICAL ATTENTION IF ANY OF THE FOLLOWING SIGNS AND SYMPTOMS APPEAR OR WORSEN AFTER INFUSION:

- Headache
- Itching
- Vomiting
- Shortness of breath
- Hives/rash
- Skin redness
- Fever
- Swelling

OTHER IMPORTANT REMINDERS:

- **Contact your nurse and prescriber** immediately if you or your child does not feel well or experiences any side effects during or after infusion.
- **XENPOZYME dosage initiation or escalation, at any time during pregnancy, is not recommended.**
- **If you are a female of reproductive potential,** your doctor will verify your pregnancy status before starting treatment with XENPOZYME.
- **Use effective contraception during treatment** with XENPOZYME and for 14 days after the last dose if XENPOZYME is discontinued.
- **If you are pregnant or plan to become pregnant,** tell your doctor right away.
- **When you receive the infusion at home:**
 - **Discuss any missed doses** with the nurse providing care, as a different nurse may be assigned during subsequent home infusions. Report the missed doses to your healthcare team and prescriber.
 - **Testing for liver enzyme levels** is recommended to be continued as part of routine clinical management of ASMD.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Allergic Reactions (Including Anaphylaxis) and Infusion-Associated Reactions (IARs)

See Boxed WARNING for more information. Your doctor may decide to give you antihistamine, anti-fever, and/or steroid medications before your infusions. Signs of allergic reactions and infusion-associated reactions (IARs) included hives, itchy skin, skin redness, rash, swelling underneath the skin, tender bumps under the skin, and localized swelling, as well as headache, vomiting, nausea, fever, and diarrhea.

Reactions may occur during and/or after the infusion. Tell your healthcare provider right away if you experience any reactions. Your healthcare provider may slow or stop the infusion or may lower the next dose.

Please see [Important Safety Information](#) and full [Prescribing Information](#) for complete details, including Boxed WARNING.

QUESTIONS? WE ARE YOUR CONNECTION FOR SUPPORT



CareConnect Case Manager

Your CareConnect Case Manager is your primary point of contact for questions about health insurance and reimbursement, and can help with care coordination such as scheduling infusions.

CareConnect Patient Education Liaison (PEL)

Your CareConnect PEL acts as a resource for ongoing questions, concerns, and support for you and your healthcare team. Your PEL can help make sure you have all the information you need, including:

- Disease and product in-service training from the Home Infusion Nursing Agency and Specialty Pharmacy
- Help with understanding what is required for home infusion regarding storage and delivery of supplies and medication
- Product and disease education, and acting as a resource for ongoing questions, concerns, and support for you and your healthcare team

Access personalized support and resources at [CareConnectPSS.com](https://www.CareConnectPSS.com) or call 1-800-745-4447 (toll free), Option 3, or email Info@CareConnectPSS.com.



IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (CONTINUED)

Elevated Transaminases Levels

XENPOZYME may be associated with elevated liver enzymes (known as transaminases) within 24 to 48 hours after infusion. Your doctor should check your liver enzyme levels with a blood test:

- within one month before starting XENPOZYME;
- within 72 hours before any infusion during the dose escalation phase, or before your next scheduled XENPOZYME infusion if you missed a dose.

Based on the results of your blood tests, your doctor may make changes to your dose or infusion schedule. Upon reaching the recommended maintenance dose, your doctor may continue to monitor your liver enzyme levels.

Please see [Important Safety Information](#) and full [Prescribing Information](#) for complete details, including **Boxed WARNING**.

INDICATION AND IMPORTANT SAFETY INFORMATION



INDICATION

XENPOZYME® (olipudase alfa-rpcp) is indicated for treatment of non-central nervous system manifestations of acid sphingomyelinase deficiency (ASMD) in adult and pediatric patients.

IMPORTANT SAFETY INFORMATION

WARNING: SEVERE ALLERGIC REACTIONS

Allergic Reactions Including Anaphylaxis

Allergic reactions, including severe reactions that may be serious or life-threatening (known as anaphylaxis), have occurred during and after XENPOZYME treatment. Tell your healthcare provider right away if you develop any reactions, and seek immediate medical care if severe reactions occur. If a severe allergic reaction occurs, your doctor may decide to discontinue XENPOZYME immediately and provide appropriate medical care. Appropriate medical support measures may be administered, and you may require close observation during and after XENPOZYME administration.

WARNINGS AND PRECAUTIONS

Allergic Reactions (Including Anaphylaxis) and Infusion-Associated Reactions (IARs)

See Boxed WARNING for more information. Your doctor may decide to give you antihistamine, anti-fever, and/or steroid medications before your infusions. Signs of allergic reactions and infusion-associated reactions (IARs) included hives, itchy skin, skin redness, rash, swelling underneath the skin, tender bumps under the skin, and localized swelling, as well as headache, vomiting, nausea, fever, and diarrhea.

Reactions may occur during and/or after the infusion. Tell your healthcare provider right away if you experience any reactions. Your healthcare provider may slow or stop the infusion or may lower the next dose.

Elevated Transaminases Levels

XENPOZYME may be associated with elevated liver enzymes (known as transaminases) within 24 to 48 hours after infusion. Your doctor should check your liver enzyme levels with a blood test:

- within one month before starting XENPOZYME;
- within 72 hours before any infusion during the dose escalation phase, or before your next scheduled XENPOZYME infusion if you missed a dose.

Based on the results of your blood tests, your doctor may make changes to your dose or infusion schedule. Upon reaching the recommended maintenance dose, your doctor may continue to monitor your liver enzyme levels.

Risk to Unborn Babies

Starting or increasing the dose of XENPOZYME is not recommended in a pregnant female as it may cause harm (birth defects) to the developing baby. If you are pregnant or plan to become pregnant, tell your doctor right away.

If you are a female of reproductive potential, your doctor will verify your pregnancy status before you start treatment with XENPOZYME. You should use effective contraception during XENPOZYME treatment and for 14 days after your last dose if XENPOZYME is discontinued.

ADVERSE REACTIONS

- Most frequently reported adverse drug reactions in adults (incidence $\geq 10\%$) were headache, cough, diarrhea, low blood pressure, and redness in the eye.
- Most frequently reported adverse drug reactions in pediatric patients (incidence $\geq 20\%$) were fever, cough, diarrhea, runny nose, abdominal pain, vomiting, headache, hives, nausea, rash, joint pain, itchy skin, fatigue, and sore throat.

Please see full [Prescribing Information](#) for complete details, including Boxed WARNING.



BE READY FOR HOME INFUSIONS WITH XENPOZYME

YOUR XENPOZYME TREATMENT CHECKLIST



- ✓ Talk to your CareConnect Case Manager and Patient Education Liaison (PEL) for help arranging home infusions.
- ✓ Follow your infusion and monitoring schedule!



- ✓ Plan ahead so you're ready for your appointment.
- ✓ If you have questions, have them ready to discuss with your doctor or infusion nurse.
- ✓ Prepare a clean space for your infusion and have some light activities to do to pass the time.



- ✓ Track your progress.
- ✓ Confirm your next infusion and monitoring appointments.
- ✓ Contact your doctor if you experience any side effects or infusion-associated reactions (IARs).

For any questions relating to CareConnect, visit [CareConnectPSS.com](https://www.CareConnectPSS.com), call 1-800-745-4447, Option 3, or email Info@CareConnectPSS.com.

INDICATION

XENPOZYME® (olipudase alfa-rpcp) is indicated for treatment of non-central nervous system manifestations of acid sphingomyelinase deficiency (ASMD) in adult and pediatric patients.

IMPORTANT SAFETY INFORMATION

WARNING: SEVERE ALLERGIC REACTIONS

Allergic Reactions Including Anaphylaxis

Allergic reactions, including severe reactions that may be serious or life-threatening (known as anaphylaxis), have occurred during and after XENPOZYME treatment. Tell your healthcare provider right away if you develop any reactions, and seek immediate medical care if severe reactions occur. If a severe allergic reaction occurs, your doctor may decide to discontinue XENPOZYME immediately and provide appropriate medical care. Appropriate medical support measures may be administered, and you may require close observation during and after XENPOZYME administration.

Please see [Important Safety Information](#) and full [Prescribing Information](#) for complete details, including **Boxed WARNING**.

sanofi

© 2024 Genzyme Corporation. All rights reserved. CareConnect Personalized Support Services is a trademark of Sanofi or an affiliate. Sanofi and Xenpozyme are registered trademarks of Sanofi or an affiliate.

MAT-US-2206163-v2.0-02/2024

Xenpozyme®
(olipudase alfa-rpcp)
For Injection, 20 mg