STAY ON TRACK WITH YOUR INFUSIONS

Xenpozyme™ (olipudase alfa-rpcp)

WELCOME TO TREATMENT WITH XENPOZYME. Your treatment is given as an intravenous infusion once every 2 weeks. No matter where you are in your infusion schedule—*whether you are starting out in dose escalation or have already reached your maintenance dose*—these tips can help you stay on track with treatment.

INFUSION BASICS

Biweekly infusions: Prioritize keeping and attending all of your infusion appointments. If you miss 3 or more infusions, you will need to return to dose escalation. Dose escalation should take place in a clinical setting to manage for the possibility of severe reactions.

Routine monitoring: Your doctor will regularly order blood tests before and possibly after infusions during dose escalation to monitor how your body is adjusting to the treatment.

MY CONTACTS

Infusion location: _____

Infusion specialist: _____ Phone: _____

TIPS FOR TREATMENT

PRE-INFUSION

- ✓ Be prepared to share your medical history.
- ✓ Put all of your **infusion** dates and times in your calendar.
- ✓ Put all of your **blood test** dates and times in your calendar.
- ✓ Let your doctor know if there is a change in your pregnancy status, if applicable.
- ✓ Prior to infusion, your doctor may decide to pretreat you or your child with anti-fever, anti-allergy, and/or steroid medications.

INFUSION DAY

- ✓ Schedule enough travel time to arrive on time or early to your appointment.
- ✓ If you have questions, make a list to discuss with your doctor.
- ✓ Prepare for your infusion by dressing comfortably and bringing something to help pass the time.
- ✓ During the infusion, let your doctor or nurse know if you or your child is experiencing any side effects.

POST-INFUSION

- ✓ Track how you are feeling.
- ✓ Write down any side effects you experience and share them with your doctor.
- ✓ Confirm your next **infusion** appointment.
- ✓ Confirm your next **blood test** appointment.

INDICATIONS AND USAGE

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 HYPERSENSITIVITY REACTIONS

Hypersensitivity Reactions Including Anaphylaxis

Hypersensitivity reactions, including severe reactions known as anaphylaxis, may occur during and after XENPOZYME treatment. You should seek immediate medical care if hypersensitivity reactions (including anaphylaxis) occur. If a severe hypersensitivity 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 throughout and full Prescribing Information, including Boxed WARNING, for XENPOZYME for complete details.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions Including Anaphylaxis

Your doctor may decide to give you antihistamine, anti-fever, and/or steroid medications before your infusions.

- If a *severe* hypersensitivity reaction (e.g., anaphylaxis) occurs, your doctor should discontinue XENPOZYME immediately and initiate appropriate medical treatment.
- If a *mild or moderate* hypersensitivity reaction occurs, your doctor may adjust or temporarily withhold your infusion rate or dose of XENPOZYME.

Hypersensitivity reactions, including anaphylaxis, have been reported in olipudase alfa-treated patients.

- Signs of hypersensitivity reactions in adults included hives, itchy skin, skin redness, rash, swelling underneath the skin, and tender bumps under the skin.
- Hypersensitivity reactions in pediatric patients included hives, itchy skin, rash, and localized swelling.

Infusion-Associated Reactions

Your doctor may decide to give you antihistamine, anti-fever, and/or steroid medications before your infusions to reduce the risk of infusion-associated reactions (IARs). However, IARs may still occur after receiving these medications.

- If *severe* IARs occur, your doctor should discontinue XENPOZYME immediately and initiate appropriate medical treatment.
- If a *mild or moderate* IAR occurs, your doctor may adjust or temporarily withhold your infusion rate or dose of XENPOZYME.

The most frequent IARs in:

- adult patients were headache, rash, vomiting, and hives;
- pediatric patients were hives, swelling, headache, nausea, fever, and vomiting.

An acute phase reaction (APR), an acute inflammatory response accompanied by elevations in inflammatory protein concentrations from blood tests, was observed.

- Most of the APRs occurred at 48 hours post infusion during the dose escalation period.
- The most common symptoms of APRs were fever, vomiting, and diarrhea.
- Your doctor can manage APRs like other IARs you may experience.

Elevated Transaminases Levels

XENPOZYME may be associated with elevated liver enzymes, known as transaminases, within 24 to 48 hours after infusion.

- Elevated transaminase levels were reported in patients during the XENPOZYME dose escalation phase in clinical trials.

To manage the risk of elevated transaminase levels, 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 levels of transaminases from your blood tests, your doctor may make changes to your dose or infusion schedule.

Upon reaching the recommended maintenance dose, transaminase testing is recommended to be continued as part of routine clinical management of ASMD.

Risk of Fetal Malformations During Dosage Initiation or Escalation in Pregnancy

XENPOZYME dosage initiation or escalation, for a female at any time during her pregnancy, is not recommended as it may increase risk of defects in the fetus. The decision to continue or discontinue XENPOZYME maintenance dosing, if you are a pregnant female, should be determined by you and your doctor and should consider your need for XENPOZYME, the potential drug-related risks to the fetus, and the potential risks due to untreated maternal ASMD disease.

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 ≥10%) were headache, cough, diarrhea, low blood pressure, and redness in the eye.
- Most frequently reported adverse drug reactions in pediatric patients (incidence ≥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, including Boxed WARNING, for XENPOZYME for complete details.

LEARN MORE AT XENPOZYME.COM

Xenpozyme™ (olipudase alfa-rpcp)

Access personalized support and resources at CareConnectPSS.com. Services are also available at **1-800-745-4447** (toll free), Option 3, or email **Info@CareConnectPSS.com**.

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