

Electronic Certificate

Version: 1 . 0

Document Number: MAT-US-2206830

Document Name: Xenpozyme Consumer ISI

Country: United States

Product: XENPOZYME

Type: Material

Sub Type:

Classification:

Certification Statement
We certify that the final electronic form of this material is in accordance with the regulations set forth by the health authority for the country of this document, and is a fair and truthful presentation of the facts about the product.

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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.

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 $\geq 10\%$) 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, rash, fatigue, and sore throat.

Please see full Prescribing Information, including Boxed WARNING, for XENPOZYME.