Xenpozyme™
(olipudase alfa-rpcp)

TALKING WITH YOUR DOCTOR ABOUT TREATMENT FOR ASMD (NON-CNS MANIFESTATIONS)

IT IS IMPORTANT TO DISCUSS WITH YOUR DOCTOR HOW ASMD IS AFFECTING YOU. THIS GUIDE CAN HELP FACILITATE A DISCUSSION AT YOUR NEXT APPOINTMENT.

ASMD=acid sphingomyelinase deficiency; CNS=central nervous system.

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 complete details.

WHAT ARE YOUR ASMD SYMPTOMS?

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ASMD symptoms vary from person to person. They can also worsen over time. That is why it is important to keep track of them and discuss them with your doctor.

WHAT ASMD SYMPTOMS ARE YOU EXPERIENCING?

HOW OFTEN DO THESE SYMPTOMS OCCUR?

☐ Not very often ☐ Somewhat often ☐ Very often

WHICH ASMD SYMPTOMS SEEM TO BE WORSENING, IF ANY?

WHAT NEW ASMD SYMPTOMS HAVE YOU BEEN EXPERIENCING SINCE YOUR LAST VISIT WITH THE DOCTOR, IF ANY?

HOW HAVE YOUR SYMPTOMS BEEN MANAGED TO DATE?

IS THERE ANYTHING ELSE YOU WOULD LIKE TO DISCUSS?

ASMD IS A GENETIC DISEASE THAT CAN RUN IN FAMILIES. WHAT QUESTIONS MIGHT YOU HAVE FOR YOUR DOCTOR ABOUT FAMILY TESTING?

SINCE ASMD IS AN INHERITED CONDITION, CONSIDER FAMILY TESTING.

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.

ASK YOUR DOCTOR ABOUT XENPOZYME—

THE FIRST AND ONLY DISEASE-SPECIFIC TREATMENT FOR ASMD (NON-CNS MANIFESTATIONS)

When it comes to non-CNS manifestations of ASMD, did you know there is only one disease-specific treatment option approved by the FDA? Here are a few questions and discussion points you can bring up with your doctor to find out if XENPOZYME is right for you or your child.

WHAT IS XENPOZYME?

XENPOZYME is an enzyme replacement therapy that provides the acid sphingomyelinase (ASM) enzyme that is deficient in people with ASMD.

WHAT RESULTS HAVE BEEN SEEN WITH XENPOZYME?

XENPOZYME is approved for the treatment of non-CNS manifestations of ASMD. XENPOZYME was studied in 3 clinical trials with adults and children. Your doctor can share information on the safety and efficacy results from the trials.

HOW IS XENPOZYME GIVEN?

XENPOZYME is given as an intravenous infusion once every 2 weeks.

HOW CAN I GET STARTED?

Ask your doctor about whether XENPOZYME is right for you or your child. You can also access personalized support and resources with CareConnectPSS®.

LEARN MORE ABOUT ASMD TREATMENT AT XENPOZYME.COM

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (CONTINUED)

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 Important Safety Information throughout and full Prescribing Information, including Boxed WARNING, for complete details.

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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Personalized Support Services

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