For the use only of a Registered Medical Practitioner or Hospital or a Laboratory

▼ Abbreviated Prescribing Information

Olipudase alfa Powder for concentrate for solution for infusion
Xenpozyme ®
20 mg in single-use vial

Name and Presentation: Xenpozyme®100 mg/vial. Each vial contains 20 mg/vial, Powder for concentrate for solution for infusion. Each 20 mg vial contains 21.2 mg of olipudase alfa. **Therapeutic indication:** Xenpozyme (Olipudase alfa) is indicated as enzyme replacement therapy for long-term treatment of non-central nervous system (CNS) manifestations of acid sphingomyelinase deficiency (ASMD) in pediatric and adult patients. **Dosage and administration:** Xenpozyme is for intravenous use only. Xenpozyme should be administered every 2 weeks by a healthcare professional. Infusions should be administered in a stepwise manner preferably using an infusion pump. After reconstitution and dilution, the solution is administered as an intravenous infusion using infusion rates, the dose should be increased according to the dose escalation regimen (Refer to the Full prescribing information for the dose escalation protocol). Maintenance phase: The recommended maintenance dosage of Xenpozyme is 3 mg/kg every 2 weeks. In patients with a body mass index (BMI) >30, the body weight that is used to calculate the dose of Xenpozyme is estimated via the following method (for dose escalation and maintenance phases). Body weight (kg) to be used for dose calculation = 30 × (actual height in m)^2. *Missed doses*: A dose is considered missed when not administered within 3 days of the scheduled date. *Home infusion during maintenance phase:* Home infusion under the supervision of a healthcare professional may be considered for patients on maintenance dose **Special Population:** Pediatric patients: The recommended starting dose of Xenpozyme is 0.03 mg/kg for pediatric patients, every 2 weeks and the dose should be subsequently increased according to the dose escalation regimen (Refer to the Full prescribing information for the dose escalation protocol). *Elderly patients:* Clinical studies with Xenpozyme included 2 patients between 65 and 75 years of age No dose adjustment is recommended for patients over the age of 65. *Hepatic and Renal impairment:* No dose adjustment is recommended in patients with renal or hepatic impairment. **Contraindications:** Xenpozyme is contraindicatedin patients with life-threatening hypersensitivity (anaphylactic reaction) to olipudase alfa or to any of the excipients when tailored desensitization was unsuccessful. **Warnings and precautions**: Infusion associated reactions (IARs) occurred in approximately 58% of patients treated with Xenpozyme in clinical studies. These IARs included hypersensitivity reactions and acute phase reactions. The most frequent IARs were headache, urticaria, pyrexia, nausea, and vomiting. *Hypersensitivity/anaphylaxis:* Hypersensitivity reactions, including anaphylaxis, have been reported in Xenpozyme treated patients. If severe hypersensitivity or anaphylaxis occurs, Xenpozyme should be discontinued immediately, and appropriate medical treatment should be initiated. Transient Transaminases elevation: Transient transaminase elevations (ALT or AST) within 24 to 48 hours after infusions were reported in 4 adult and 7 pediatric patients during the dose escalation phase with Xenpozyme in clinical studies. Transaminases (ALT and AST) levels should be obtained within 1 month prior to Xenpozyme treatment initiation. During dose escalation or upon resuming treatment following missed doses, transaminases levels should be obtained within 72 hours prior to the next scheduled Xenpozyme infusion (If either the baseline or a pre-infusion transaminase level is >2 times the ULN during dose escalation, then additional transaminase levels should be obtained within 72 hours after the end of the infusion). Upon reaching the recommended maintenance dose, transaminase testing can be performed as part of routine clinical management of ASMD. Drug interactions: No drug interaction studies have been performed. Because olipudase alfa is a recombinant human protein, no cytochrome P450 mediated drug-drug interactions are expected. Functional inhibitors of acid sphingomyelinase: Based on published in silico and in vitro data, tricyclic antidepressants and some cationic amphiphilic drugs including antihistaminic drugs may decrease olipudase alfa activity. The clinical relevance of this functional inhibition is not known. This theoretical interaction should be considered when Xenpozyme is prescribed concomitantly with chronic systemic treatment with functional inhibitors of acid sphingomyelinase. **Fertility, pregnancy and lactation:** Women of childbearing potential. It is recommended to perform a pregnancy test prior to treatment initiation with Xenpozyme. There are no available data on Xenpozyme use in pregnant women. There are no available data on the presence of Xenpozyme in human milk, effects on milk production or on the breastfed infant. Xenpozyme should not be used during breastfeeding unless the potential benefits to the mother outweigh the potential risks, including those to the breastfed child. No human data are available to determine potential effects of Xenpozyme on fertility in males and females. **Effects on ability to drive:** No studies on the effects on the ability to drive and use machines have been performed. Because dizziness and hypotension have been reported in clinical studies, Xenpozyme may have a minor influence on the ability to drive and use machines. **Undesirable effects:** The most frequently reported adverse drug reactions (ADRs) (occurring in ≥10% of Xenpozyme patients) were headache, pyrexia, urticaria, nausea, vomiting, abdominal pain, myalgia, pruritus, and C-reactive protein increased. **Overdose:** There has been no overdose of olipudase alfa reported in clinical studies Using a dose escalation regimen, intravenous doses of Xenpozyme up to 3 mg/kg have been administered in clinical studies.

Special precautions for storage: Store in a refrigerator between 2°C and 8°C (36°F and 46°F). AFTER RECONSTITUTION AND DILUTION: The reconstituted solution and diluted solutions of Xenpozyme should be used immediately. If immediate use is not possible, the reconstituted solution may be stored for up to 24 hours at 2°C to 8°C (36°F to 46°F), or 12 hours at room temperature (up to 25°C/77°F). After dilution, the solution can be stored for up to 24 hours at 2°C to 8°C (36°F to 46°F) followed by 12 hours (including infusion time) at room temperature (up to 25°C/77°F).

For full and latest prescribing information, refer to company website www.sanofi.in.

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