Important information for the healthcare professional

Olipudase alfa

This patient is receiving olipudase alfa, an enzyme replacement therapy for the treatment of non-central nervous system manifestations of ASMD in pediatric and adult patients with type A/B or type B.

This medicine can cause infusion-associated reactions including severe hypersensitivity and anaphylaxis that may appear any time during or even after treatment. Assess patients for signs and symptoms of infusion-associated reactions. Early diagnosis and appropriate management are essential to minimise any consequences of these types of reactions.

Important contact information

Patient's name:

Prescribing/treating physician:
- Name:

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- Contact (telephone):

.....

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Hospital/centre:
- Name:

.....

- Emergency contact (telephone):

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Important information for women of childbearing potential including adolescents

It is recommended to perform a pregnancy test prior to treatment initiation.
If you are pregnant, breast-feeding, planning to breast-feed, think you may be pregnant, or are planning to have a baby, ask your doctor or nurse for advice before using this medicine.
It is advised to use effective contraception during treatment and for 14 days after the last dose if olipudase alfa is discontinued.
Please speak to your doctor or nurse for advice before using this medicine.

Important side effects

Olipudase alfa is given as an intravenous infusion.
In rare cases, during or after infusion, patients may experience a severe allergic reaction, which must be treated immediately.
Contact your specialist straight away if you develop any signs and symptoms of infusion-associated reactions, severe hypersensitivity or anaphylaxis that are listed below that may appear or worsen during or after infusion:

- Shortness of breath/choking
- Dizziness, weakness, or fainting
- Weak and rapid pulse
- Nausea, vomiting, or diarrhea
- Flushed and pale skin, hives, itching,headache, urticaria, athralgia, myalgia, pyrexia, nausea, vomiting, abdominal pain

Please report any events to your healthcare professional.

Reporting adverse drug reactions

If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Alternatively adverse events can be reported via email to UK-drugsafety@sanofi.com

By reporting side effects you can help provide more information on the safety of this medicine.

XENPOZYME (olipudase alfa)▲

PATIENT CARD

This card contains important safety information about your treatment.
Carry this card with you at all times, especially when you travel, whenever you go to the Accident and Emergency department, or when you see another doctor.
Please show this card to any physician or nurse involved in your medical care.
Please see the SmPC for complete information
https://www.medicines.org.uk/emc/.

▲This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the 'Reporting Adverse Drug Reactions' section for how to report side effects.

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