

What is XENPOZYME?

XENPOZYME is a medication that contains an artificial enzyme olipudase alfa as the active substance.

It is used as a replacement for an enzyme called acid sphingomyelinase (ASM), which is lacking in patients with ASM deficiency (ASMD). In such patients, the activity of ASM is either lower than normal or absent completely, which can cause various symptoms.

<XENPOZYME is indicated as 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>.

Patient's name:

treating physician:

- Name:

- Contact (telephone):

Hospital/centre:

- Name:

- Emergency contact (telephone):

XENPOZYME (olipudase alfa)

PATIENT CARD

This document is approved by
The Executive Directorate of Pharmacovigilance, at SFDA

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This Patient Card contains important information you need to be aware of when receiving treatment with XENPOZYME. Please refer to the patient leaflet for complete information.



General guidance

Please show this card to any physician or nurse involved in your medical care.

XENPOZYME
(olipudase alfa)

Important side effects

XENPOZYME 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.

Seek urgent medical attention if any of the following signs and symptoms 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

Please report any events to your treating physician.

For women of childbearing potential

Discuss the need for contraception measures with your treating physician.

Please refer to the SmPC/Product information for complete information

Contact your treating physician if you suspect you might be pregnant or if you plan pregnancy.

- For Medical Information, Please contact: +966-12-669-3318, ksa.medicalinformation@sanofi.com
- In case of any drug related adverse events, please contact:
The National Pharmacovigilance Center (NPC)
Call Center: 19999 - E-mail: npc.drug@sfd.gov.sa
Website: <https://ade.sfd.gov.sa/>

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