Reporting side effects

This Patient Card contains important information you need to be aware of when receiving treatment with olipudase. Please refer to the patient information leaflet for complete information. This Medicine is subject to additional monitoring. This will allow quick identification of new safety information.

Please report suspected side effects to the MHRA through the Yellow Card scheme, via the Yellow Card website www.mhra.gov.uk/yellowcard, the free Yellow Card app available in Apple App Store or Google Play Store. Alternatively, you can call 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

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

Side effects can also be reported to Sanofi: Tel: 0800 0902314. email: uk-drugsafety@sanofi.com

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.

Seek urgent medical attention if any of the following signs and symptoms appear or worsen during or after infusion.

If symptoms are severe or worsen stop the infusion. These could be signs of severe hypersensitivity or anaphylaxis which can be life-threatening:

- 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, abdominal pain

Please report any events to your healthcare professional.

Important information for women of childbearing potential including adolescents

This medicine may harm your baby. It is recommended to perform a pregnancy test prior to treatment initiation.

It is advised to use an effective method of birth control (contraception) during treatment and for 14 days after the last dose if olipudase alfa is discontinued.

If you are planning to get pregnant, or think you are pregnant and/or planning to breastfeed speak to your doctor before using this medicine.

What is olipudase alfa?

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.

It is used for type A/B or type B paediatric or adult patients to treat symptoms of ASMD not related to the brain.

Important contact information

Patient's name:

Prescribing/treating physician:
- Name:

Contact (telephone):

Hospital/centre:
- Name:
- Emergency contact (telephone):

XENPOZYME (olipudase alfa) ▲
PATIENT CARD

Carry this card with you at all times, especially when you travel, whenever you go to an Accident and Emergency Department, or when you see anyone other than your usual healthcare professional.
Please show this card to any doctor, nurse, pharmacist or other healthcare professional involved in your medical care.
For more complete information the Summary of Product Characteristics is available at https://www.medicines.org.uk/emc/product/14839/smpc

▲ 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 Side Effects' section for how to report side effects.
This material fulfills the conditions of the marketing authorisation and has been approved by the Medicines and Healthcare products Regulatory Agency (MHRA).

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