Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

ELELYSO®

Powder for solution for infusion

Each vial with powder contains:
taliglucerase alfa 200 Units

Inactive ingredients and allergens: see section 2 under 'Important information about some of this medicine's ingredients' and section 6 'Further information'.

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. WHAT IS THIS MEDICINE INTENDED FOR?

ELELYSO is a hydrolytic lysosomal glucocerebroside-specific enzyme given by injection that is indicated for long-term enzyme replacement therapy for adults and pediatric patients above 2 years with a confirmed diagnosis of Type 1 Gaucher disease.

Therapeutic group: Recombinant active hydrolytic lysosomal enzyme, β-glucocerebrosidase

2. BEFORE USING THIS MEDICINE

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients in this medicine (see section 6).

Special warnings regarding use of the medicine
Before treatment with ELELYSO, tell your doctor if:

- You previously had a severe hypersensitivity reaction following intravenous infusion with ELELYSO.
- You are pregnant or breastfeeding.

Tests and follow-up
In patients who developed anti-drug antibodies or who had hypersensitivity reactions after treatment with ELELYSO or after treatment with other enzyme replacement therapy, it may be necessary to monitor the antibody levels.

Drug interactions
If you are taking or have recently taken, other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist.

Pregnancy and breastfeeding
If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, consult your doctor before taking this medicine.

Driving and using machines
The use of this medicine may lead to dizziness and, therefore, do not drive or operate dangerous machines until you know how the medicine affects you.

Important information about some of this medicine's ingredients
ELELYSO contains sodium
This medicine contains less than 1 mmol sodium (23 mg) in each vial and can therefore be defined as being essentially "sodium free".

3. HOW TO USE THIS MEDICINE?

Always use this preparation according to your doctor's instructions.
Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.
The dosage and treatment regimen will be determined by your doctor only.

ELELYSO is administered by intravenous infusion after being prepared by a medical staff member/under supervision. Do not swallow.

Do not exceed the recommended dose.

If you have accidentally used a higher dosage
If you have received an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

Adhere to the treatment as recommended by your doctor.

Even if your health improves, do not stop taking this medicine without consulting your doctor or pharmacist, in order to prevent your disease from worsening.

Do not take medicines in the dark! Check the label and dose <u>each time</u> you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of ELELYSO may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Hypersensitivity reactions, including anaphylaxis that may be life-threatening
Serious hypersensitivity reaction, including anaphylaxis, appeared in some of the patients treated with ELELYSO. Signs and symptoms of anaphylaxis include: hives (urticaria), hypotension, flushing, wheezing, chest tightness, nausea, vomiting and dizziness. These reactions occurred during ELELYSO infusion. If anaphylaxis occurs, discontinue the treatment immediately and receive appropriate medical treatment.
Signs and symptoms of hypersensitivity include: itching, angioedema, flushing, erythema, rash, nausea, vomiting, cough, chest tightness, and throat irritation. These reactions have occurred up to three hours after the start of infusion.
Treatment for hypersensitivity reactions is determined according to the severity of the reaction and include slowing or temporary interruption of the infusion and/or administration of antihistamines, fever reducers, and/or corticosteroids for mild reactions.
Your doctor may decide to administer preventative treatment with antihistamines and/or corticosteroids before administering the ELELYSO infusion in order to prevent hypersensitivity reactions.

If serious hypersensitivity reactions occur, immediately stop the infusion and receive appropriate treatment.

Immunogenicity
There is the potential for the development of anti-drug antibodies in the body. The relationship between immunogenicity and a hypersensitivity reaction is not completely clear.

Side effects (at a frequency of ≥ 5%) in patients 19 years and older who did not receive previous treatment:
Headache, joint pain, fatigue, nausea, dizziness, abdominal pain, itching, flushing, vomiting, hives (urticaria).

Side effects in patients 16 years and younger who did not receive previous treatment:
The most common side effect (≥ 10%) is vomiting.
Additional side effects include hypersensitivity reactions, severe vomiting, gastrointestinal inflammation, throat irritation and chest discomfort.

Side effects (at a frequency of ≥ 10%) in patients who switched from treatment with Imiglucerase to treatment with ELELYSO:
Joint pain, headache and pain in the extremities.

Additional side effects that were reported from follow-up after marketing of the preparation:
Vomiting, diarrhea, fatigue, anaphylaxis, Type III immune-mediated fixed drug eruption, back pain.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects or by using the link: https://sideeffects.health.gov.il.

5. HOW TO STORE THE MEDICINE?

- Prevent poisoning! This and any other medicine should be kept in a closed place, out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- Keep refrigerated (2°C-8°C). Protect from light.
- Use immediately after reconstituting and diluting. If it cannot be used immediately, the reconstituted/diluted preparation can be stored for up to 24 hours at a temperature of 2°C-8°C when it is protected from light. Do not freeze. Unused solution should be discarded.

6. FURTHER INFORMATION

In addition to the active ingredient, this medicine also contains:
mannitol, sodium citrate, polysorbate 80, citric acid.

What the medicine looks like and contents of the pack:

ELELYSO is marketed as a powder in a vial for one-time use. Each package contains one vial.

Registration holder and address: Pfizer Pharmaceuticals Israel Ltd., 9 Shenkar St., Herzliya Pituach 46725.

Registration number of the medicine in the Ministry of Health's National Drug Registry: 148-67-33413

Revised in 04/2024.

The following information is intended for medical or healthcare professionals only:

Preparation Instructions

ELELYSO should be reconstituted, diluted, and administered under the supervision of a healthcare professional.

Prepare ELELYSO according to the following steps using aseptic technique.

a. Determine the number of vials to be reconstituted based on the patient's weight in kg and the recommended dose. Round the number of vials up to the next whole number.

b. Remove the required number of vials from the refrigerator. Do not leave these vials at room temperature longer than 24 hours prior to reconstitution. Do not heat or microwave these vials.

c. Reconstitute each vial of ELELYSO with 5.1 mL of Sterile Water for Injection to yield a reconstituted product with a concentration of 40 units/mL and an extractable volume of 5 mL.

(1) Upon reconstitution, mix vials gently. DO NOT SHAKE.
(2) Prior to further dilution, visually inspect the reconstituted solution in the vials for particulate matter and discoloration. The solution should be clear and colorless. Discard if particulate matter is present or the solution is discolored.

d. Withdraw the calculated dose of drug from the appropriate number of vials and dilute with 0.9% Sodium Chloride Injection, USP, to a final volume of 100 to 200 mL. Discard any unused reconstituted solution.
    i. For pediatric patients, use a final volume of 100 to 120 mL.
    ii. For adult patients, may use a final volume of 130 to 150 mL. However, if the volume of reconstituted product alone is equal to or greater than 130 to 150 mL, then the final volume should not exceed 200 mL.

e. Mix the diluted solution gently. DO NOT SHAKE. Since this is a protein solution, slight flocculation (described as translucent fibers) occurs occasionally after dilution.
f. Discard any unused diluted solution.

Administration Instructions

After reconstitution and dilution, administer via intravenous infusion over a minimum of 60 minutes and with an in-line low protein-binding 0.2 micron filter.

- For pediatric patients who weigh (based on actual body weight):
    - Less than 30 kg, use an infusion rate of 1 mL/minute.
    - Greater than or equal to 30 kg, use an initial infusion rate of 1 mL/minute. After tolerability to ELELYSO is established, may increase the infusion rate to a maximum of 2 mL/minute.
- For adult patients: use an initial infusion rate of 1.2 mL/minute. After tolerability to ELELYSO is established, may increase the infusion rate to a maximum of 2.2 mL/minute.