

PART III: CONSUMER INFORMATION

Pr[®]**ELELYSO**[®]
Taliglucerase alfa

This leaflet is part III of a three-part "Product Monograph" published when ELELYSO was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about ELELYSO. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION**What the medication is used for:**

ELELYSO is an enzyme replacement therapy for pediatric and adult patients with Gaucher disease.

What it does:

Gaucher disease is a genetic disorder caused by a missing or defective enzyme name glucocerebrosidase. When this enzyme is missing or does not work properly, a substance called glucocerebroside builds up inside cells in the body. The build-up of this substance causes the signs and symptoms found in Gaucher disease.

Signs of the disease are one or more of the following:

- Spleen or liver enlargement
- A low number of red blood cells (anaemia)
- A tendency to bleed easily caused by a low blood platelet count
- Bone disease

When it should not be used:

Do not use ELELYSO if you are allergic to taliglucerase alfa or to any ingredient in the formulation or component of the container.

What the medicinal ingredient is:

Taliglucerase alfa

What the important nonmedicinal ingredients are:

Citric acid anhydrous, Mannitol, Polysorbate 80, Sodium citrate.

What dosage forms it comes in:

ELELYSO 200 units is presented as a powder for solution for infusion. ELELYSO is supplied in a 13.5mL vial.

WARNINGS AND PRECAUTIONS

BEFORE you use ELELYSO talk to your doctor or pharmacist if:

- You have previously experienced an adverse reaction related to the infusion or allergic reaction with another enzyme replacement therapy for Gaucher disease
- You have allergies to this drug or its ingredients or components of the container; or if you are allergic to carrots
- You are pregnant or plan to become pregnant or are breast-feeding

INTERACTIONS WITH THIS MEDICATION

No interaction studies have been performed. Please inform your doctor if you are using any other medicinal products.

PROPER USE OF THIS MEDICATION**Usual dose:**

Dosage is individualized for each patient. ELELYSO is only used under the supervision of a health care professional. If you are tolerating your infusions well in the clinic, your doctor may suggest that the infusion be administered at home by a health care professional.

The initial doses of ELELYSO range from 30 units/kg to 60 units/kg of body weight.

ELELYSO is given once every two weeks.

Overdose:

There is no experience with overdose of taliglucerase alfa with doses over 78 units/kg.

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you have missed an ELELYSO infusion, please contact your doctor.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, ELELYSO can cause side effects, although not everybody gets them.

Most side effects are mild to moderate and generally are associated with the infusion however side effects may be serious and may need treatment.

Very common side effect (these are likely to affect more than 10 in every 100 people):

- Headache
- Abdominal pain
- Pain in extremity, Joint pain
- Fatigue
- Vomiting
- Back pain
- Itching

Common side effects (these are likely to affect between 1 and 10 in every 100 people):

- Allergic reactions
- Dizziness
- Flushing
- Throat irritation
- Nausea

- Redness
- Rash
- Bone pain
- Infusion related reaction
- Infusion site pain
- Swelling
- Weight increase

If you experience any of these symptoms, please tell your doctor immediately.

The most serious adverse reactions seen were allergic reactions. If you have an allergic reaction following administration of ELELYSO, contact your doctor immediately. If a severe allergic reaction occurs, immediately discontinue ELELYSO. If you experience an allergic reaction your doctor or nurse may continue treatment by slowing the infusion rate and/or giving you medicines such as antihistamines, antipyretics or corticosteroids. Pre-treatment with antihistamines and/or corticosteroids may prevent subsequent reactions.

HOW TO STORE IT

Keep out of reach and sight of children.

Unopened vial: store under refrigeration (2°-8°C). Keep the vial in the outer carton in order to protect from light. Do not use after the expiry date printed on the label.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- \$ Report online at www.healthcanada.gc.ca/medeffect
- \$ Call toll-free at 1-866-234-2345
- \$ Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 1908C
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at: <http://www.Pfizer.ca> or by contacting the sponsor, Pfizer Canada Inc., at: 1-800-463-6001

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