

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **ELELYSO**[®]

Taliglucerase alfa

Read this carefully before you start taking **Elelyso** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Elelyso**.

What is Elelyso used for?

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

How does Elelyso work?

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

What are the ingredients in Elelyso?

Medicinal ingredients: Taliglucerase alfa

Non-medicinal ingredients: Citric acid anhydrous, Mannitol, Polysorbate 80, Sodium citrate.

Elelyso comes in the following dosage forms:

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

Do not use Elelyso if:

- you are allergic to taliglucerase alfa or to any ingredient in the formulation or component of the container.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Elelyso. Talk about any health conditions or problems you may have, including if you:

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

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

No interaction studies have been performed.

How to take Eleyso:

Usual dose:

Dosage is individualized for each patient. Eleyso 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 Eleyso range from 30 units/kg to 60 units/kg of body weight.

Eleyso is given once every two weeks.

Overdose:

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

If you think you, or a person you are caring for, have taken too much Eleyso, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

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

What are possible side effects from using Eleyso?

These are not all the possible side effects you may have when taking Eleyso. If you experience any side effects not listed here, tell your healthcare professional.

Like all medicines, Eleyso 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.

The most serious adverse reactions seen were allergic reactions. If you have an allergic reaction following administration of Eleyso, contact your doctor immediately. If a severe allergic reaction occurs, immediately discontinue Eleyso. 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.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Headache		X	
Abdominal pain		X	
Pain in extremity, Joint pain		X	
Fatigue		X	
Vomiting		X	
Back pain		X	
Itching		X	
COMMON			
Allergic reactions		X	
Dizziness		X	
Flushing		X	
Throat irritation		X	
Nausea		X	
Redness		X	
Rash		X	
Bone pain		X	
Infusion related reaction		X	
Infusion site pain		X	
Swelling		X	
Weight increase		X	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

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.

Keep out of reach and sight of children.

If you want more information about Elelyso:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website <http://www.pfizer.ca>, or by calling 1-800-463-6001.

This leaflet was prepared by Pfizer Canada ULC.

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