

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Elelyso.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Elelyso against the benefits it is expected to have for you.

Ask your doctor or pharmacist if you have any concerns about using this medicine.

Keep this leaflet as you may need to read it again.

What Elelyso is used for

Elelyso is an Enzyme Replacement Therapy which is used to treat Type 1 Gaucher disease in adults and children (2 to 17 years of age) with at least one of the following signs of the condition:

- Spleen or liver enlargement
- A low number of red blood cells (anaemia)
- A tendency to bleed easily caused by a low blood platelet count. (platelets stop blood loss by forming a plug inside a blood vessel).

Elelyso has not been studied in Type 2 Gaucher disease.

How Elelyso works

Gaucher disease is a genetic disorder caused by a missing or defective enzyme named 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 material causes the signs and symptoms found in Gaucher disease. Elelyso is designed to replace the missing or defective enzyme, glucocerebrosidase, in patients with Type 1 Gaucher disease.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Before you are given Elelyso

When you must not use it

Do not use Elelyso if you have an allergy to:

- Any medicine containing taliglucerase alfa rpc
- Any of the ingredients listed at the end of this leaflet
- Other Enzyme Replacement Therapies such as Cerezyme® or Vpriv®.

Talk to your doctor if you are not sure whether you should start using this medicine.

Before you start to use it

Tell your doctor if you have previously experienced an infusion-related reaction or allergic reaction to other Enzyme Replacement Therapy for Gaucher disease.

If you have an infusion-related reaction you may be given additional medicines to treat or help prevent future reactions. These medicines may include antihistamines,

antipyretics (medicine used to lower high temperature/fever), and corticosteroids.

Tell your doctor if you have an allergy to carrots.

Taliglucerase alfa rpc is manufactured using carrot cells.

Tell your doctor if you are on a low salt diet.

Patients on a controlled salt (sodium) diet should consider that Elelyso is given in a solution containing sodium chloride.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you have experienced difficulty breathing.

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

If you have not told your doctor about any of the above, tell him/her before you start taking Elelyso.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including:

- All prescription medicines
- All medicines, vitamins, herbal supplements or natural therapies you buy without a prescription from a pharmacy, supermarket, naturopath or health food shop.

Some medicines may be affected by Elelyso or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines. Your doctor will advise you.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

How Elelyso is given

Elelyso is given through a drip into a vein (by intravenous infusion). The drip should be given over at least 60 minutes. It may be given to you at a hospital, a clinic or, at your home, if your doctor considers this appropriate.

Elelyso should only be administered under the supervision of a doctor (or healthcare professional) who is knowledgeable in the treatment of Gaucher disease.

Home administration may be considered for patients who tolerate their infusion well. For home administration, Elelyso should be administered by a healthcare professional trained in managing infusion-related reactions, under the direction of a doctor.

How much to use

Your doctor will decide the dosage and the frequency of the dose suitable for you.

If you forget to use it

If you miss a dose of Elelyso, tell your doctor.

If you receive too much (overdose)

Your doctor will supervise how much Elelyso you are given. If you think that you have been given too much Elelyso tell your doctor or nurse immediately.

If you need further advice, contact the Poisons Information Centre (telephone 13 11 26).

If you stop using Elelyso

Tell your doctor if you intend to stop the treatment.

Patients should be aware that there are potential serious consequences in stopping the treatment and you are advised to discuss this with your doctor before doing so.

If you have any further questions on the use of this medicine, ask your doctor.

While you are using Elelyso

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are being given Elelyso.

Tell any other doctors, dentists, and pharmacists who treat you that you are using this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are using this medicine.

It may affect other medicines used during, or after surgery.

If you become pregnant while being given this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are using this medicine.

It may interfere with the results of certain tests.

Keep all of your doctor or clinic appointments so that your progress can be checked.

Your doctor may do certain tests, including blood tests, from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

Do not stop using your medicine or lower the dosage without checking with your doctor.

If you stop using it suddenly, your condition may worsen or you may have unwanted side effects.

It is important to have your infusion at the appropriate time to make sure the medicine is effective in treating your condition.

Things to be careful of

Be careful driving or operating machinery until you know how Elelyso may affect you.

Be careful when drinking alcohol while you are using this medicine.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being given Elelyso.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

It can be difficult to tell whether side effects are the result of using Elelyso, effects of your condition or side effects of other medicines

you may be taking. For this reason it is important to tell your doctor of any change in your condition.

Do not be alarmed by the list of side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Infusion-related reactions

Common side effects occurring during infusion or within 24 hours of receiving Elelyso include:

- Muscle pain, joint pain or spasm
- Headache
- Vomiting
- Stomach pains
- Pain in hands or feet
- Itching
- Allergic reaction
- Nausea
- Limb swelling
- Throat irritation
- Redness of skin
- Urticaria (slightly elevated patches on the skin) or hives
- Swelling of the eyes
- Feeling hot (flushing)
- Feeling uncomfortable in your chest
- Diarrhoea
- Shaking
- Rash.

Other common side effects

- Dizziness
- Bone pain
- Back pain
- Infusion site pain
- Tiredness
- Weight increase.

Tell your doctor if...

Severe allergic reactions are less common side effects of Elelyso but may be serious.

Tell your doctor immediately if you experience any of the allergic reactions listed below:

- Difficulty breathing or shortness of breath
- Swelling of the face, lips, tongue or throat.

If you experience any of the allergic reactions listed above go to hospital immediately as you may require urgent medical attention.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Some of these side effects can only be found when your doctor does tests from time to time to check your progress.

After using Elelyso

Storage

Keep out of the reach and sight of children.

Unopened vials

Store in a refrigerator (2°C to 8°C). Do not freeze. Protect from light. Keep the vial in the outer carton until use.

Do not use Elelyso after the expiry date printed on the label. The expiry date refers to the last date of that month.

Reconstituted and diluted solutions

Elelyso should be mixed (reconstituted) and diluted just before use and used immediately. If not used immediately, in-use storage times and conditions of the reconstituted solution and the diluted solution prior to use are the responsibility of the user.

The reconstituted vial and the diluted solution that is made from the reconstituted vial can be stored for a combined time of not more than 24 hours at 2°C to 8°C under protection from light after the initial reconstitution step.

Disposal

If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Elelyso 200 units is presented as a powder for injection (a single vial in a carton).

Elelyso is supplied as a white to off-white powder that may form a cake. After reconstitution the solution is a clear, colourless liquid. The reconstituted solution must be further diluted for infusion.

Ingredients

The active ingredient in Elelyso is taliglucerase alfa rpc.

The other ingredients are:

- Mannitol
- Sodium citrate dihydrate
- Polysorbate 80.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Supplier

Pfizer Australia Pty Ltd
Sydney, NSW
Toll Free Number: 1800 675 229
www.pfizer.com.au

Australian registration numbers

AUST R 207695.

Date of preparation

This leaflet was prepared in June 2019.

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