

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Elelyso?

Elelyso contains the active ingredient taliglucerase alfa rpc and 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: a spleen or liver that is larger than expected; 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). For more information, see Section [1. Why am I using Elelyso?](#) in the full CMI.

2. What should I know before I use Elelyso?

Do not use if you have ever had an allergic reaction to any medicine containing taliglucerase alfa rpc, other Enzyme Replacement Therapies such as Cerezyme® or Vpriv®, to carrots, or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have previously experienced a reaction during an infusion or allergic reaction to other Enzyme Replacement Therapy for Gaucher disease; if you are on a low salt diet; if you have experienced difficulty breathing; if you take any other medicines; or if you are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Elelyso?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Elelyso and affect how it works. For more information, see Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Elelyso?

Elelyso should only be given under the supervision of a doctor (or healthcare professional) who is knowledgeable in the treatment of Gaucher disease. Your doctor will decide the dosage and the frequency of the dose suitable for you.

More instructions can be found in Section [4. How do I use Elelyso?](#) in the full CMI.

5. What should I know while using Elelyso?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you are using Elelyso.If you become pregnant while being given Elelyso, tell your doctor immediately.If you are going to have surgery, tell the surgeon or anaesthetist that you are using Elelyso.If you are about to have any blood tests, tell your doctor that you are using Elelyso.Keep all of your doctor or clinic appointments so that your progress can be checked.
Things you should not do	<ul style="list-style-type: none">Do not stop using this medicine, or lower the dosage, without checking with your doctor.
Driving or using machines	<ul style="list-style-type: none">Be careful driving or operating machinery until you know how Elelyso affects you.
Drinking alcohol	<ul style="list-style-type: none">Be careful when drinking alcohol while you are using Elelyso.
Looking after your medicine	<ul style="list-style-type: none">Store unopened vials in a refrigerator (2°C to 8°C). Do not freeze. Protect from light.

For more information, see Section [5. What should I know while using Elelyso?](#) in the full CMI.

6. Are there any side effects?

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 (itchy, slightly elevated patches on the skin) or hives; swelling of the eyes; feeling hot; feeling uncomfortable in your chest; diarrhoea; shaking or rash. Other common side effects include dizziness; bone pain; back pain; pain at the site on your body the infusion was given; tiredness; weight increase. For more serious side effects and further information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Elelyso[®] (elle-lee-lie-so)

Active ingredient(s): *taliglucerase alfa rpc* (tal-lee-glue-sir-raise al-far r-p-c)

Consumer Medicine Information (CMI)

This leaflet provides important information about using Elelyso. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Elelyso.**

Where to find information in this leaflet:

- [1. Why am I using Elelyso?](#)
- [2. What should I know before I use Elelyso?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Elelyso?](#)
- [5. What should I know while using Elelyso?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Elelyso?

Elelyso contains the active ingredient taliglucerase alfa rpc, 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:

- A spleen or liver that is larger than expected
- 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 or inherited condition 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 people with Type 1 Gaucher disease.

2. What should I know before I use Elelyso?

Do not use Elelyso if you have an allergy to:

1. Any medicine containing taliglucerase alfa rpc
2. Any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
3. Other Enzyme Replacement Therapies such as Cerezyme[®] or Vpriv[®].

Before you start to use it

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

If you have a reaction during the infusion 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/or 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.

People with Type 1 Gaucher disease on a controlled salt (sodium) diet should consider that Elelyso is given in a solution containing sodium chloride.

Tell your doctor if you have experienced difficulty breathing.

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

Check with your doctor if you:

- have any allergies to any other medicines, foods, preservatives or dyes
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

If you become pregnant while taking Elelyso, tell your doctor immediately.

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Elelyso and affect how it works.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Elelyso.

4. How do I use Elelyso?

How it is given

Elelyso is given through a drip into a vein (by intravenous infusion). The drip should be given over a period of 60 to 120 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 given under the supervision of a doctor (or healthcare professional) who is knowledgeable in the treatment of Gaucher disease.

Infusions given at home may be considered for people who tolerate their infusion well. For infusions given at home, Elelyso should be given by a healthcare professional trained

in managing reactions during the infusion, 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.

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.

5. What should I know while using Elelyso?

Things you should 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 should 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Elelyso affects you.

Drinking alcohol

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

Looking after your medicine

Keep it where young children cannot reach it.

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.

The solution in the vial containing the dissolved powder and the diluted solution that is made from the solution in the 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.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

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

Common infusion side effects	What to do
<ul style="list-style-type: none">• 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 (itchy, slightly elevated patches on the skin) or hives• swelling of the eyes• feeling hot (flushing)• feeling uncomfortable in your chest• diarrhoea• shaking• rash	Speak to your doctor if you have any of these common side effects during the infusion and they worry you.

Other common side effects

Other common side effects	What to do
<ul style="list-style-type: none">dizzinessbone painback painpain at the site on your body the infusion was giventirednessweight increase	Speak to your doctor if you have any of these common side effects and they worry you.

More serious side effects

More serious side effects	What to do
Signs of severe allergic reactions: <ul style="list-style-type: none">difficulty breathing or shortness of breathswelling of the face, lips, tongue or throat	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these more serious side effects.

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

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Elelyso contains

Active ingredients (main ingredient)	taliglucerase alfa rpc
Other ingredients (inactive ingredients)	mannitol sodium citrate dihydrate polysorbate 80

Do not use this medicine if you are allergic to any of these ingredients.

What Elelyso 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 (dissolving the powder) the solution is a clear, colourless liquid. The reconstituted solution must be further diluted for infusion.

AUST R 207695

Who distributes Elelyso

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedicalinformation.com.au

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