PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

ELELYSO® 200 units/vial powder for solution for intravenous infusion

Taliglucerase alfa

Contains sugar

Each vial of ELELYSO contains 206,7 mg of mannitol

Read all of this leaflet carefully before you are given ELELYSO

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

What is in this leaflet

1. What ELELYSO is and what it is used for
2. What you need to know before you use ELELYSO
3. How to use ELELYSO
4. Possible side effects
5. How to store ELELYSO
6. Contents of the pack and other information

1. What ELELYSO is and what it is used for

ELELYSO is a medicine that contains the active substance taliglucerase alfa.

ELELYSO is an enzyme replacement therapy used for the treatment of 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.

2. What you need to know before you use ELELYSO

ELELYSO should not be administered to you

- if you are severely hypersensitive (allergic) to taliglucerase alfa, other enzyme replacement therapies for Gaucher disease or any of the other ingredients of ELELYSO (listed in section 6).
- if you have a known allergy to carrots because ELELYSO is manufactured using carrot cells.

Warnings and precautions

Tell your doctor or health care provider before being given the injection:

- if you have previously experienced an infusion-related reaction or allergic reaction to enzyme replacement therapy for Gaucher disease. Your treatment may need to be changed or discontinued if severe reactions occur while receiving ELELYSO.
- if you have experienced difficulty breathing because additional testing may be required during use of ELEYSO.
- if you are over 65 years old because you may need to start ELELYSO at a lower dose.

Children

ELELYSO treatment has similar safety and effectiveness in children and adults.

Other medicines and ELELYSO

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine. If you become pregnant while using this medicine, tell your doctor immediately.

Driving and using machines

Be careful driving or operating machinery until you know how ELELYSO may affect you. ELELYSO may cause dizziness.

It is not always possible to predict to what extent ELELYSO may interfere with the daily activities of a patient. You should ensure that you do not engage in the above activities until you are aware of the measure to which ELELYSO affects you.

ELELYSO contains sodium and mannitol

Tell your doctor if you are on a low salt (sodium) diet. Patients on a controlled salt diet should consider that ELELYSO contains sodium and it is given in a solution containing sodium chloride.

ELELYSO contains mannitol and may have a laxative effect.

3. How to take ELELYSO

Do not share medicines prescribed for you with any other person.

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.

You will not be expected to give yourself ELELYSO. It will be given to you by a person who is qualified to do so.

ELELSYO should only be administered under the supervision of a doctor or health care provider who is knowledgeable in the treatment of Gaucher disease.

Home administration may be considered for patients who tolerate their infusions well. For home administration, ELELYSO should be administered by a health care provider trained in managing infusion-related reactions, under the direction of a doctor.

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

Your doctor may do certain tests, including blood tests, during ELELYSO treatment to make sure it is working and to prevent unwanted side effects.

If you take more ELELYSO than you should

Since a health care provider will administer ELELYSO, he / she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to use ELELYSO

Since a health care provider will administer ELELYSO, it is unlikely that the dose will be missed. If you miss a dose of ELELYSO, tell your doctor.

If you stop using ELELYSO

Tell your doctor if you intend to stop ELELYSO 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.

4. Possible side effects

ELELYSO can have side effects.

Not all side effects reported for ELELYSO are included in this leaflet. Should your general health

worsen or if you experience any untoward effects while taking ELELYSO, please consult your health care provider for advice.

If any of the following happens, stop using ELELYSO and tell your doctor immediately or go to the casualty department at your nearest hospital:

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

These are all very serious side effects. If you have them, you may have had a serious reaction to ELELYSO. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Allergic reaction
- Headache
- Dizziness
- Feeling hot (flushing)
- Throat irritation
- Vomiting
- Stomach pain
- Nausea
- Itching
- Redness of skin
- Rash
- Joint pain
- Pain in hands or feet
- Bone pain
- Back pain
- Infusion site pain

- Tiredness
- Limb swelling
- Infusion-related reaction
- Weight increase

The following additional side effects have been reported in post-marketing surveillance:

- Urticaria (slightly elevated patches on the skin) or hives

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reactions Reporting Form"**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of ELELYSO.

5. How to store ELELYSO

Store all medicines out of reach of children.

Unopened vials

- Store at or between 2°C to 8°C (in a refrigerator).
- Do not freeze.
- Protect from light. Keep the vial in the outer carton until use.
- Do not use after the expiry date stated 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.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ELELYSO contains

The active substance is taliglucerase alfa.

The other ingredients are citric acid anhydrous, mannitol, sodium citrate and Polysorbate 80.

What ELELYSO looks like and contents of the pack

ELELYSO is presented as a powder for solution for infusion (a single glass vial enclosed in a cardboard 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.

Holder of Certificate of Registration

Pfizer Laboratories (Pty) Ltd

85 Bute Lane

Sandton 2196

South Africa

Tel: +27(0)11 320 6000 / 0860 734 937 (Toll-free South Africa)

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