Myozyme® (alglucosidase alfa) Home Infusion Guide for Patients/Caregivers

This educational material is part of the marketing authorisation and has been approved by the Health Products Regulatory Authority (HPRA)

The patient/caregiver guide contains the following elements:

- *Information on the risk of infusion-associated reactions (IARs) notably hypersensitivity and anaphylactic reactions, including their signs and symptoms and the recommended actions when symptoms occur.*
- *An Annex with The Infusion Diary to follow up infusions.*

About this document

Read all of this information carefully.

Keep this information in an easily accessible place; you may need to read it again.

- If you have further questions, ask your prescriber and the healthcare professional (HCP) administering the infusion.
- This medicine has been prescribed for you or your dependent. Do not pass it on to others even if their symptoms are the same as yours as it may harm them.
- If you experience any side effects, you and/or your caregiver must notify your prescriber or infusion HCP.

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CONTENTS

ABBREVIATIONS

GAA	Acid alpha-glucosidase
HCP	Healthcare Professional (doctor, nurse, others)
IAR	Infusion-associated reaction

1. Pompe Disease and Treatment

Together with your prescriber, you have decided to start home infusion therapy with alglucosidase alfa. The objective of this document is to provide you with information on the signs and symptoms related to infusion-associated reactions (IARs) and recommended actions for the management of the side effects when symptoms occur.

Pompe disease is a rare disease in which the first symptoms can occur at any age from birth to late adulthood. A common symptom at all ages is skeletal muscle weakness, which may progress into mobility and lung problems.

Patients with Pompe disease have low or absent levels of an enzyme called 'acid alpha-glucosidase' (GAA). This enzyme is normally responsible for the breakdown of a sugary compound called "glycogen", which is made of many units of "glucose", and as a result, abnormal deposits of glycogen build up in different organs.

Alglucosidase alfa is an artificially produced enzyme which is intended to replace the natural enzyme GAA that is lacking or not active enough in patients with Pompe disease. Alglucosidase alfa is used for the long-term treatment of patients who have a confirmed diagnosis of Pompe disease.

Refer to the Patient Information Leaflet that came with your medicine for additional information. Patient Information Leaflets are also available on the www.medicines.ie website.

2. Home Infusion

The decision to receive home treatment may be made by your prescriber and you/the caregiver, after initial infusions at the hospital to make sure there are no problems with the infusion.

Home infusion is the responsibility of the prescriber.

Home infusions are considered when you, or the person under your care, is tolerating infusions well and has no history of moderate or severe IARs for a few months.

It is the responsibility of the prescriber to ensure a safe administration of medication to you or the patient under your care. Your home infusion should be supervised by an appropriately trained HCP e.g. nurse who should always be available during the home infusion and for a specified time after infusion. The dose you receive is based on your body weight. It will be given to you once every 2 weeks through a drip into a vein (by intravenous infusion).

If you or the person under your care experiences side effects during the home infusion, the infusion should be stopped immediately and appropriate medical treatment should be initiated ***(see section 3)***.

3. Infusion-Associated Reactions (IARs)

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

3.1 Alglucosidase alfa side effects

Side effects were mainly seen while patients were being given the medicine or shortly after ("infusion-associated reactions ").

Some of these infusion-associated reactions were serious or life-threatening. Life threatening reactions, including very severe generalised allergic reactions and anaphylactic shock, have been reported in some patients. Symptoms of such reactions include low blood pressure, very fast heart rate, difficulty breathing, vomiting, facial, lip or tongue swelling, hives or rash.

Some patients have experienced infusion-related side effects in the form of flu-like symptoms, which lasted for a few days after completion of the infusion. Beware that some patients have experienced side effects several hours after the infusion ended.

Should you experience any reaction like this, please tell your infusion HCP and prescriber immediately (contact details should be available in your 'Infusion Diary' included at the end of this guide.)

For a full list of possible side effects, read the Patient Information Leaflet that came with your medicine, and keep it handy. Patient Information Leaflets are also available on www.medicines.ie.

3.2 Managing IARs

Your doctor will decide how to continue with the treatment, or if you need to receive pre-treatment medication to prevent some of these side effects (e.g. antihistamines and/or corticosteroids to manage immune responses, and/or antipyretics to reduce fever). In some instances, your doctor may decide to continue treatment at the hospital until your safety has been ensured, or even revert infusions to the hospital permanently.

It is possible that your prescriber has decided to give you other medicines to prevent mild and moderate reactions.

If you experience any severe side effects during the infusion, your infusion HCP will completely stop the infusion and follow the guidance pre-established by your prescriber.

In case of a mild or moderate side effect, your infusion HCP will temporarily stop the infusion and restart at a lower infusion rate depending on the persistence of the symptoms. If the symptoms don't disappear, your infusion HCP might decide to fully stop the infusion for that day.

4. The use of "The Infusion Diary" to record infusions and document side effects

"The Infusion Diary" is included as an **annex** to this patient/caregiver guide.

The Infusion Diary is where you or the infusion HCP may record all your infusions and any side effects, before, during or after the infusion.

Should you experience any side effects, please tell your doctor immediately. You can also report side effects directly to HPRA Pharmacovigilance, website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

Annex:
The Infusion Diary

The Infusion Diary

Infusion Diary for recording the infusions with alglucosidase alfa General data to be completed by the prescriber. Emergency Number:	
Patient:	Name:
	Address:
	Eircode:
	Phone number:
Patient caregiver:	Name:
	Address:
	Eircode:
	Phone number:
HCP administering alglucosidase alfa	Name:
	Institution:
	Eircode:
	Phone number:
Prescriber (the HCP prescribing alglucosidase alfa)	Name:
	Institution:
	Eircode:
	Phone number:

The Infusion Diary

Administration details (to be completed by the prescriber)	Alglucosidase alfa administered since (DD.MM.YYYY):
	First infusion at home (DD.MM.YYYY):
	Reasons for alglucosidase alfa infusion at home:
	Alglucosidase alfa dosing regimen (dose, frequency, and rate of infusion):
	Additional notes:
Emergency treatment details (to be completed by the prescriber)	Necessary actions in the event of a serious infusion associated reaction:
	1. Stop the infusion. 2. Call the emergency services number _____ 3. Call the prescriber

The Infusion Diary

To be completed by either the infusion HCP or patient/carer.

Date of infusion:	
Name of the Healthcare Professional administering the infusion	
Patient's general health condition: specific problems/remarks	
Dose	
Batch number/Number of vials used	
Duration of administration	
Rate of administration	
Problems/Remarks (related to infusion)	
Any side effects?	
Before the infusion?	__Yes __No
During the infusion?	__Yes __No
After the infusion?	__Yes __No
Comments (e.g. description, severity, etc.):	

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