

# IMPORTANT SAFETY INFORMATION

## For patients and caregivers who receive home infusion of Myozyme (alglucosidase alfa)

VERSION NO. 1.0

*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 Appendix with the Patient/Caregiver's 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 treating physician and the healthcare professional 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 treating physician or infusion HCP.

# Contents

<b>01</b>	<b>Home Infusion</b>	<b>4</b>
<b>02</b>	<b>Side Effects Management</b>	<b>4</b>
<b>03</b>	<b>The Use of “The Infusion Diary”</b>	<b>6</b>

## ABBREVIATIONS

GAA: Acid alpha-glucosidase

HCP: Healthcare Professional (doctor, nurse, others)

IAR: Infusion associated reaction

The processes presented in this document serve as overall guidance but are subject to local medical practice and national rules and regulations.

Refer to the Patient Information Leaflet that came with your medicine for additional information.

## 1. HOME INFUSION

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Currently, in some countries, people suffering from Pompe disease and treated with alglucosidase alfa receive their infusions at home. **The decision to receive home treatment should be made by your treating physician and you/the caregiver, after initial infusions at the hospital to make sure there are no problems with the infusion.**

Home infusion of alglucosidase alfa allows you/the patient to receive treatment within the living environment which increases comfort and flexibility of infusion timing. It also prevents you/the patient from needing to travel to the hospital every other week and allows you/the patient to follow a normal schooling program and/or organise social and professional activities more easily. Home infusion also facilitates arranging treatment around family and friends.

**Home infusion is the responsibility of the treating physician.** Your physician has given you this patient/caregiver guide because of their belief that you, or the patient under your care, can have alglucosidase alfa administered at home and you also prefer this option. **It is the responsibility of the treating physician to ensure a safe administration to the patient.** This should be checked and documented by the treating physician. The patient and their family should consent to transitioning to home infusion, and the home facility must be suitable to perform the infusions.

**An appropriately trained infusion HCP will perform the infusion at your home.**

## 2. SIDE EFFECT MANAGEMENT

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

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

**Some of these infusion related side effects 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 doctor immediately.**

Please report suspected side effects (ADRs) to the MHRA through the Yellow Card scheme. You can report via:

- the Yellow Card website <https://yellowcard.mhra.gov.uk>
- the free Yellow Card app available from the [Apple App Store](#) or [Google Play Store](#)
- some clinical IT systems (EMIS/SystemOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm. You can leave a message outside of these hours.

When reporting, please provide as much information as possible.

Side effects should also be reported to Sanofi: Tel: 0800 0902314;  
Email: [uk-drugsafety@sanofi.com](mailto:uk-drugsafety@sanofi.com)

By reporting side effects, you can help provide more information on the safety of this medicine.

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, corticosteroids and/or antipyretics). 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 treating physician 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 treating physician.**

**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. Your infusion HCP may consider giving you additional medicines. If the symptoms don't disappear, your infusion HCP might decide to fully stop the infusion for that day.

For the full list of all side effects reported with alglucosidase alfa, please see the Patient Information Leaflet.

**In the event that you do not feel well due to the medication during the home infusion, the medication will be immediately stopped by the infusion HCP. The treating physician, their medical designate, and/or the country-specific national emergency number may be contacted immediately depending on the severity of the side effect. Subsequent infusions may need to occur in a clinical setting.**

The treating physician and/or the country-specific national emergency number must also be phoned if an Infusion Associated Reaction (IAR) occurs shortly after completion of the infusion. Any IAR must be recorded in the "Patient/Caregiver Infusion Diary" included at the end of this guide.

### 3. THE USE OF "THE INFUSION DIARY"

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

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

Should you experience any side effects, please tell your doctor immediately.

Please report suspected side effects (ADRs) to the MHRA through the Yellow Card scheme. You can report via:

- the Yellow Card website <https://yellowcard.mhra.gov.uk>
- the free Yellow Card app available from the [Apple App Store](#) or [Google Play Store](#)
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Email: [uk-drugsafety@sanofi.com](mailto:uk-drugsafety@sanofi.com)

## Annex: The Infusion Diary

### Infusion Diary for recording the infusions with alglucosidase alfa

General data to be completed by the treating physician.

Emergency Number:

Patient:	Name:
	Address:
	Phone number:
	Post code:
	Phone number:
Patient caregiver:	Name:
	Address:
	Phone number:
	Post code:
	Phone number:
HCP administering alglucosidase alfa	Name:
	Institution:
	Phone number:
	Post code:
	Phone number:
Treating physician (the HCP prescribing alglucosidase alfa)	Name:
	Institution:
	Phone number:
	Post code:
	Phone number:
	Emergency number:

## The Infusion Diary

Date of infusion:	
Name of the Healthcare Professional administering the infusion	
Any side effects to the infusion?	
During the infusion?	<input type="checkbox"/> Yes <input type="checkbox"/> No
After the infusion?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Comments:	
Date of infusion:	
Name of the Healthcare Professional administering the infusion	
Any side effects to the infusion?	
During the infusion?	<input type="checkbox"/> Yes <input type="checkbox"/> No
After the infusion?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Comments:	
Date of infusion:	
Name of the Healthcare Professional administering the infusion	
Any side effects to the infusion?	
During the infusion?	<input type="checkbox"/> Yes <input type="checkbox"/> No
After the infusion?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Comments:	

## The Infusion Diary

Date of infusion:	
Name of the Healthcare Professional administering the infusion	
Any side effects to the infusion?	
During the infusion?	__Yes __No
After the infusion?	__Yes __No
Comments:	
Date of infusion:	
Name of the Healthcare Professional administering the infusion	
Any side effects to the infusion?	
During the infusion?	__Yes __No
After the infusion?	__Yes __No
Comments:	
Date of infusion:	
Name of the Healthcare Professional administering the infusion	
Any side effects to the infusion?	
During the infusion?	__Yes __No
After the infusion?	__Yes __No
Comments:	

## The Infusion Diary

Date of infusion:	
Name of the Healthcare Professional administering the infusion	
Any side effects to the infusion?	
During the infusion?	<input type="checkbox"/> Yes <input type="checkbox"/> No
After the infusion?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Comments:	
Date of infusion:	
Name of the Healthcare Professional administering the infusion	
Any side effects to the infusion?	
During the infusion?	<input type="checkbox"/> Yes <input type="checkbox"/> No
After the infusion?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Comments:	
Date of infusion:	
Name of the Healthcare Professional administering the infusion	
Any side effects to the infusion?	
During the infusion?	<input type="checkbox"/> Yes <input type="checkbox"/> No
After the infusion?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Comments:	

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Date of infusion:	
Name of the Healthcare Professional administering the infusion	
Any side effects to the infusion?	
During the infusion?	__Yes __No
After the infusion?	__Yes __No
Comments:	
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Name of the Healthcare Professional administering the infusion	
Any side effects to the infusion?	
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After the infusion?	__Yes __No
Comments:	
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Name of the Healthcare Professional administering the infusion	
Any side effects to the infusion?	
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During the infusion?	__Yes __No
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During the infusion?	__Yes __No
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Name of the Healthcare Professional administering the infusion	
Any side effects to the infusion?	
During the infusion?	__Yes __No
After the infusion?	__Yes __No
Comments:	

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Name of the Healthcare Professional administering the infusion	
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Name of the Healthcare Professional administering the infusion	
Any side effects to the infusion?	
During the infusion?	__Yes __No
After the infusion?	__Yes __No
Comments:	
Date of infusion:	
Name of the Healthcare Professional administering the infusion	
Any side effects to the infusion?	
During the infusion?	__Yes __No
After the infusion?	__Yes __No
Comments:	

