Aldurazyme® (laronidase) Home Infusion Guide for Patient/Caregiver including an Infusion Diary

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

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About this document

Read all of this information carefully.

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

- If you have further questions, ask your treating physician 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 the patient's as it may harm them.
- If you experience any side effects, you and/or your caregiver must notify your treating physician or infusion HCP.

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ABBREVIATIONS

CNS	:	Central Nervous System
GAGs	:	Glycosaminoglycans
HCP	:	Health Care Professional (doctor, nurse, others)
IAR	:	Infusion Associated Reaction
MPS I	:	Mucopolysaccharidosis type I
PIL	:	Patient Information Leaflet

1. MPS I DISEASE AND TREATMENT

Together with your prescribing physician, you have decided to start home infusion therapy with laronidase. 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. Also included is an Infusion Diary that should be used to record the infusions and document any product-related IARs, including allergic-type hypersensitivity reactions before, during or after the infusion.

MPS I is a rare, inheritable, genetic condition that may present itself in both children and adults. **MPS disease** is a rare disease in which first symptoms can become evident at any age from birth to early adulthood. Usually doctors notice symptoms early in life. However, since MPS I symptoms are quite common in children with other diseases, they sometimes get overlooked and diagnosis may take longer.

Patients with MPS I disease have low or no levels of an enzyme called 'alpha-L-iduronidase'. This enzyme is normally responsible for the breakdown of complex sugary compounds named "glycosaminoglycans" or "GAGs", and as a result, these substances build up in organs and damage them, causing the symptoms of MPS I. The non-neurological symptoms of MPS I can be an enlarged liver, stiff joints that make moving more difficult, reduced lung volume, heart disease and eye disease.

Laronidase is an artificially produced enzyme which is intended to replace the natural enzyme alpha-L-iduronidase that is lacking in patients with MPS I disease. Laronidase is used for the long-term treatment of the non-neurological manifestations of MPS I disease in those individuals with a confirmed diagnosis. It is important to note that laronidase can't address the neurological manifestations of the disease, because it can't cross the natural barrier that protects the central nervous system (CNS).

Refer to the Patient Information Leaflet (PIL) of laronidase for additional information, available on www.medicines.ie.

2. HOME INFUSION

Your prescribing physician will assess if home infusion is appropriate for you. **The decision to receive home treatment should be made by your prescribing physician and you/your caregiver, with a period of initial infusions performed at the hospital to make sure you have no problems during the infusions.**

Your prescribing physician has given you this patient/caregiver guide because they consider you or the patient under your care, can safely have laronidase administered at home. 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. The decision to transition to home infusion will be done following evaluation of your home facility to ensure it is suitable to perform the infusions.

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

2.1 DOSAGE AND ADMINISTRATION

The recommended dosage regimen of laronidase is 100 U/kg body weight given **once every week** as an intravenous infusion. The initial infusion rate of 2 U/kg/h may be gradually increased every fifteen minutes, if tolerated, to a maximum of 43 U/kg/h. The total volume of the administration should be delivered in approximately 3 – 4 hours.

Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

3. INFUSION-ASSOCIATED REACTIONS (IARS)

Like all medicines, laronidase treatment may cause side effects, although not everybody experiences them.

Side effects were mainly seen while patients were receiving the infusion of laronidase or shortly after (known as IARs). Beware that some patients have experienced adverse reactions several hours after the infusion ended.

3.1 INFORMATION ON THE RISK OF HYPERSENSITIVITY REACTIONS INCLUDING THE SIGNS AND SYMPTOMS RELATED TO INFUSION-ASSOCIATED REACTIONS (IARS)

Some of these IARs were serious or life-threatening. Life threatening reactions, including very severe generalised allergic reactions and anaphylactic shock, have been reported in some patients.

Symptoms may include:

- inability of lungs to work properly (respiratory failure/distress)
- high-pitched breathing sound (stridor) and other disorders due to obstruction of airways
- rapid breathing, excessive contraction of the airway muscles causing breathing difficulty (bronchospasm)
- lack of oxygen in body tissues (hypoxia)
- low blood pressure
- slow heart rate
- itchy rash (urticaria)
- swelling of the throat or face

These reactions may be particularly severe if you have a pre-existing MPS I-related upper airway obstruction.

Some patients have experienced IARs in the form of flu-like symptoms, which lasted for a few days after completion of the infusion.

For a full list of possible side effects, read the PIL that came with your medicine. An electronic copy of the PIL is also available on the www.medicines.ie website.

Should you experience any reaction please contact your doctor immediately.

Reporting of side effects:

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the Patient Information Leaflet. By reporting side effects you can help provide more information on the safety of this medicine. You can report side effects directly to HPRA Pharmacovigilance, website www.hpra.ie.

Side effects can also be reported to Sanofi: Tel: 01 403 5600; E-mail to: IEPharmacovigilance@sanofi.com.

3.2 RECOMMENDED ACTIONS IF SYMPTOMS OCCUR

Your doctor will decide how to continue with the treatment, or if you need to receive pre-treatment medication to prevent some of these adverse reactions (e.g. anti-inflammatory medicines like antihistamines and corticosteroids 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 in the hospital permanently.

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

If you have a severe side effect during an infusion, your infusion HCP will stop the infusion and follow the guidance provided by your prescribing physician.

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

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 prescribing physician, and/or 112 might be contacted immediately depending on the severity of the side effect. Subsequent infusions may need to occur in a clinical setting.

The infusion HCP or patient/caregiver should phone the prescribing physician and/or 112 if any IAR, particularly hypersensitivity reactions occuring shortly after completion of the infusion. Any IAR must be recorded in the "Infusion Diary", included at the end of this guide.

4. THE USE OF "THE INFUSION DIARY" TO RECORD INFUSIONS AND DOCUMENT SIDE-EFFECTS

As an **annex** to this patient guide is included ***"The Infusion Diary".***

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

Should you experience any reaction, please tell your doctor immediately. You can report side effects directly to HPRA Pharmacovigilance; website www.hpra.ie. Side effects can also be reported to Sanofi: Tel: 01 403 5600 e-mail to: IEPharmacovigilance@sanofi.com.

Annex 1: Infusion Diary

Infusion Diary for recording the infusions with laronidase General data to be completed by the prescribing physician. Emergency Number:	
Patient:	Name:
	Address:
	Phone number:
	EIR CODE /City:
Patient caregiver:	Name:
	Address:
	Phone number:
	EIR CODE /City:
Infusion HCP administering laronidase	Name:
	Institution:
	Phone number:
	EIR CODE /City:
Prescribing physician (the HCP prescribing laronidase)	Name:
	Institution:
	Phone number:
	EIR CODE /City:
	Emergency number:

To be completed by infusion HCP and/or patient/caregiver:

Date of infusion:	
Name of the HCP administering the infusions	
Any reactions to the infusion?	
Before the infusion?	__Yes __No
During the infusion?	__Yes __No
After the infusion?	__Yes __No
Comments (e.g. side effect description, severity, etc.):	

Date of infusion:	
Name of the HCP administering the infusions	
Any reactions to the infusion?	
Before the infusion?	__Yes __No
During the infusion?	__Yes __No
After the infusion?	__Yes __No
Comments (e.g. side effect description, severity, etc.):	

Date of infusion:	
Name of the HCP administering the infusions	
Any reactions to the infusion?	
Before the infusion?	__Yes __No
During the infusion?	__Yes __No
After the infusion?	__Yes __No
Comments (e.g. side effect description, severity, etc.):	

Date of infusion:	
Name of the HCP administering the infusions	
Any reactions to the infusion?	
Before the infusion?	__Yes __No
During the infusion?	__Yes __No
After the infusion?	__Yes __No
Comments (e.g. side effect description, severity, etc.):	

Date of infusion:	
Name of the HCP administering the infusions	
Any reactions to the infusion?	
Before the infusion?	__Yes __No
During the infusion?	__Yes __No
After the infusion?	__Yes __No
Comments (e.g. side effect description, severity, etc.):	

Date of infusion:	
Name of the HCP administering the infusions	
Any reactions to the infusion?	
Before the infusion?	__Yes __No
During the infusion?	__Yes __No
After the infusion?	__Yes __No
Comments (e.g. side effect description, severity, etc.):	

Date of infusion:	
Name of the HCP administering the infusions	
Any reactions to the infusion?	
Before the infusion?	__Yes __No
During the infusion?	__Yes __No
After the infusion?	__Yes __No
Comments (e.g. side effect description, severity, etc.):	

Date of infusion:	
Name of the HCP administering the infusions	
Any reactions to the infusion?	
Before the infusion?	__Yes __No
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After the infusion?	__Yes __No
Comments (e.g. side effect description, severity, etc.):	

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Name of the HCP administering the infusions	
Any reactions to the infusion?	
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After the infusion?	__Yes __No
Comments (e.g. side effect description, severity, etc.):	

Date of infusion:	
Name of the HCP administering the infusions	
Any reactions to the infusion?	
Before the infusion?	__Yes __No
During the infusion?	__Yes __No
After the infusion?	__Yes __No
Comments (e.g. side effect description, severity, etc.):	

Date of infusion:	
Name of the HCP administering the infusions	
Any reactions to the infusion?	
Before the infusion?	__Yes __No
During the infusion?	__Yes __No
After the infusion?	__Yes __No
Comments (e.g. side effect description, severity, etc.):	

Date of infusion:	
Name of the HCP administering the infusions	
Any reactions to the infusion?	
Before the infusion?	__Yes __No
During the infusion?	__Yes __No
After the infusion?	__Yes __No
Comments (e.g. side effect description, severity, etc.):	

Date of infusion:	
Name of the HCP administering the infusions	
Any reactions to the infusion?	
Before the infusion?	__Yes __No
During the infusion?	__Yes __No
After the infusion?	__Yes __No
Comments (e.g. side effect description, severity, etc.):	

Date of infusion:	
Name of the HCP administering the infusions	
Any reactions to the infusion?	
Before the infusion?	__Yes __No
During the infusion?	__Yes __No
After the infusion?	__Yes __No
Comments (e.g. side effect description, severity, etc.):	