

CIPAGLUCOSIDASE ALFA HOME INFUSION THERAPY

Manual for patients with Pompe disease who receive home infusion of POMBILITI ▼ (cipaglucosidase alfa)

VERSION 2.0

Some people may have side-effects when taking this medicine. If you have any unwanted side-effects you should talk to your doctor, pharmacist or other healthcare professional. This includes any possible side-effects not listed in this leaflet. Also, you can help make sure medicines remain as safe as possible by reporting unwanted side-effects using the Yellow Card Scheme via www.mhra.gov.uk/yellowcard or by searching for MHRA Yellow Card in the Google Play or Apple App Store. Alternatively, you can also report side-effects to Amicus Medical Information on: Tel: **08082346864**; or email: drugsafety@amicusrx.com.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See www.mhra.gov.uk/yellowcard for how to report side effects.

IMPORTANT

This patient manual contains important safety information you need to be aware of when receiving treatment with cipagluco­sidase alfa/miglustat. Read all of this information carefully before you start home infusion.

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

- If you have further questions, ask your treating physician.
- This medicine has been prescribed for you. 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 nurse.
- For further information please refer to the package leaflet provided with your medicine and available online. For cipagluco­sidase alfa; www.medicines.org.uk/emc/product/14898/pil and for miglustat; www.medicines.org.uk/emc/product/14904/pil

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1

HOME INFUSION SAFETY CONSIDERATIONS

Together with your treating physician, you have decided to start home infusion therapy with cipagluco­sidase alfa. The objective of this document is to provide you with guidance on how to receive cipagluco­sidase alfa at home. The processes presented in this document serve as overall guidance but are subject to local medical practice and national rules and regulations. Your treating physician will provide you with the details that are applicable to your situation.

1.1

Pompe Disease and Treatment

Pompe disease is a very rare genetic disorder. It affects how your body uses glycogen, a type of carbohydrate stored in cells for energy. Normally, there’s an enzyme called alpha-glucosidase that helps break down glycogen into glucose, which our body can use for energy. But in Pompe disease, there isn’t enough of this enzyme, so glycogen builds up in different parts of your body, especially in the muscles. This causes the cells not to work properly and makes the muscles weak, which can lead to serious problems if not treated. The Pompe disease enzyme, α-glucosidase (also known as GAA), is one of those that helps to break down a substance called glycogen.

Pompe disease is usually treated by giving an infusion of enzyme replacement therapy (ERT), so that the glycogen is not allowed to build-up in your cells. ERT works by replacing the non-functioning or missing GAA with functioning GAA. Cipagluco­sidase alfa is a new ERT – this replaces the enzyme that is insufficient in Pompe disease. It is delivered by an infusion and has been specially designed to target the cells in your muscles. Miglustat is a capsule that you swallow before the administration of intravenous cipagluco­sidase alfa. This helps to ensure that the ERT gets to where it needs to be, in the muscles, so it can help clear the build-up of glycogen.



Refer to the cipagluco­sidase alfa and miglustat Package Leaflet for additional information.

1.2

Home Infusion

It may be possible for people suffering from Pompe disease and treated with cipagluco­sidase alfa to receive their infusions at home.

→ **The decision to receive home treatment should be made by you and your treating physician after initial infusions at the hospital to make sure you have no problems with the infusion. Typically, your physician will want to ensure that you are tolerating your infusions well in a hospital or clinic setting for a few months before deciding you are eligible for home infusion.**

Home infusion of cipagluco­sidase alfa will make it possible for you to receive treatment within your own living environment which increases comfort and flexibility of infusion timing. This does not require spending time travelling to and from the hospital, and home infusion may also facilitate arranging treatment around family and friends.

→ **The home infusion will take place under the direction of your treating physician and will be delivered by an appropriately trained infusion healthcare professional/nurse who will monitor you during and after each infusion.**



Note: The dose and rate of the infusion while at home must follow the guidelines provided by your treating physician as noted in the infusion diary and must not be changed without the prior agreement of your treating physician and supervision of the infusion healthcare professional/nurse.

1.3

Safety Assessments (side effects and medication errors)

Like all medicines, this medicine can cause side effects, although not everybody gets them. In clinical studies side effects were mainly seen while patients were being given the medicine or shortly after (“infusion related reactions”). Most of the infusion-related reactions were mild or moderate. Some of these infusion-related side effects may become serious and life-threatening.

→ **Symptoms of serious or life-threatening infusion-related reactions include:**

difficulty breathing, bloating, fever, chills, dizziness, skin redness, itchy skin and rash

→ **Symptoms of serious or life-threatening allergic reactions include:**

rash, puffy eyes, prolonged difficulty breathing, cough, swelling of the lips, tongue or throat, itchy skin and hives

Your doctor may decide to lower the infusion rate or give you additional medicines to prevent such reactions from occurring again.

→ For the full list of all side effects reported with cipagluco­sidase alfa, see the Package Leaflet.

- In the event that you do not feel well due to the medication during the home infusion or shortly after the infusion, you must ask your home infusion provider to immediately stop the medication. The treating physician, their medical designate, or the emergency services (see instructions in the infusion diary) must be contacted immediately. Subsequent infusions may need to occur in a hospital or clinic setting until your prescribing physician is satisfied that you are tolerating the infusions well.
- If you feel unwell for any other reason (e.g. have a cold or flu-like illness) you should inform your physician or home infusion nurse. Your infusion may need to be rescheduled if you are otherwise unwell.
- Any symptoms or side effects should also be recorded in the infusion diary.

If you become aware that a mistake was made in the preparation and/or administration of cipagluco­sidase alfa, please inform the infusion healthcare professional/nurse or the treating physician to determine appropriate action before starting or continuing with the infusion. In case you feel the treatment is not efficacious, please contact your treating physician.

1.4 Reporting Side-effects

Some people may have side-effects when taking these medicines. If you have any unwanted side-effects you should talk to your doctor, infusion healthcare professional/nurse or other healthcare professional. This includes any possible side-effects not listed in the Package Leaflet.

→ Also, you can help make sure medicines remain as safe as possible by reporting any unwanted side-effects. You can report side effects using the Yellow Card Scheme via www.mhra.gov.uk/yellowcard or by contacting Amicus Medical Information on: Tel: 08082346864; or email: drugsafety@amicusrx.com

2 ORGANISATION OF TREATMENT AT HOME

The organisation of treatment at home should be performed under the supervision of the treating physician. Your treating physician will be responsible for organising the treatment at home. The processes presented in this document serve as an overall guidance but are subject to local medical practice and national rules and regulations.

2.1 Patient

- You and/or your caregiver(s) have been informed by the treating physician about the treatment to be provided at home, the associated risks, the possible complications, and the provision of medical assistance at home.
- You and/or your caregiver(s) have an understanding of Pompe disease and are able to recognise side effects and understand the procedures to be followed should they occur.
- The home environment must be conducive to the provision of the home infusion therapy including a clean environment with electricity, water, telephone access, refrigeration, and physical space to support storage of infusion supplies.
- You have been informed that the infusion should always be administered in the presence of an adequately trained adult (infusion healthcare professional/nurse).
- You must be physically and mentally able to undergo the infusions at home. The treating physician is responsible for determining whether you may receive cipagluco­sidase alfa infusions at home.
- You have accessible blood veins that allow an infusion needle to be inserted or you have a central venous access device
- You and/or your caregiver(s) must agree that you receive the treatment at home.

2.2 Treating Physician

- The treating physician is responsible for determining the dose, the infusion rate, the pre-infusion treatment, and the emergency treatment, to be described in the Infusion Diary. Any changes must be clearly communicated to the patient and/or caregiver(s) and described in the Infusion Diary.

- **The home infusion will take place under the responsibility of the treating physician.**
This educational material will be provided to you if your treating physician decides that you are eligible for home infusion treatment.
- The treating physician **is responsible for setting up communication lines** in case immediate medical attention is required. This should be described in the Infusion Diary.
- **Appropriate scheduling and monitoring of the infusions** is the responsibility of the treating physician in collaboration with the infusion healthcare professional/nurse.

2.3 Infusion Healthcare Professional/Nurse

- The infusion healthcare professional/nurse will have a **coordinating task** together with the treating physician and you and/or your caregiver(s) in organising the treatment at home.
- The infusion healthcare professional/nurse is **qualified to give intravenous (IV) infusions**.
- The infusion healthcare professional/nurse has been **trained in administering cipagluco­sidase alfa**.
- The infusion healthcare professional/nurse is **aware of the possible side effects** (including serious allergic reactions) and the actions to be taken should they occur.
- The infusion healthcare professional/nurse will **strictly follow the prescribed method of preparation and administering** cipagluco­sidase alfa as stated in the healthcare professional guide for home infusion.
- The infusion healthcare professional/nurse will **strictly follow the prescribed dose and infusion rate** of cipagluco­sidase alfa as stated in the Healthcare professional guide for home infusion.
- The infusion healthcare professional/nurse will **record each administration** of cipagluco­sidase alfa in the Infusion Diary.
- **Appropriate scheduling and monitoring of the infusions** is the responsibility of the treating physician and infusion healthcare professional/nurse.

2.4 Pre-treatment and Emergency Treatment

- If necessary, your treating physician will prescribe pre-treatment medication. Your treating physician will include the information on this medication in the Infusion Diary.
- Your treating physician will prescribe medication to respond to an emergency situation, if necessary. Your treating physician will include the information on this medication in the Infusion Diary. This emergency medication should be available during the infusions at home.

2.5 The Infusion Diary

- You have been provided an infusion diary by your physician. This will serve as a means of communication for everyone involved in administering cipagluco­sidase alfa at home.
- The Infusion diary must be kept at your home and will be kept up to date by you, your caregiver(s), your treating physician and/or the infusion healthcare professional/nurse.
- The prescribed dose and infusion rate of cipagluco­sidase alfa as stated in the Infusion diary should be strictly followed. The treating physician is responsible for describing the dose and the infusion rate, as well as any changes.
- Each administration of cipagluco­sidase alfa at home should be recorded in the Infusion Diary.
- You and/or your caregiver(s) must take the Infusion diary along to the hospital at each appointment for a check-up and bring it home afterwards.
- The infusion healthcare professional/nurse records the findings and actions from the initial interview and you, your caregiver(s) or the infusion healthcare professional/nurse notes all relevant information from subsequent visits in the Infusion diary.
- In the Infusion diary, the treating physician clearly states what has to be done and administered in the event of an infusion side effect. In case of any reaction to an infusion, the infusion needs to be stopped.
- Any infusion associated side effect and/or medication error should be recorded in the Infusion diary.

3 TRAINING ON PREPARATION AND ADMINISTRATION OF CIPAGLUCOSIDASE ALFA

The initial instructions will be given at your Pompe treatment centre. The level of support required for home infusion will be discussed and agreed by you and/or your caregiver(s) and your treating physician.

- Your treating physician is responsible for the organisation of the home infusion and needs to agree upon the home infusion procedure.
- Each administration of cipagluco­sidase alfa should be recorded in the Infusion diary.
- The infusion should always be administered in the presence of an adequately trained healthcare professional, experienced in the handling of infusion-associated reactions and medication errors.

4

HOW TO ADMINISTER CIPAGLUCOSIDASE ALFA

4.1

How is cipagluco­sidase alfa and miglustat given?

WHAT HAPPENS AT EACH TREATMENT?

- The number of 65mg capsules of miglustat you will need to take will depend on your body weight. Your doctor will tell you how many capsules you should take and your home infusion healthcare professional/nurse will check that you have taken these approximately one hour before the start of your cipagluco­sidase alfa infusion. The capsules should be swallowed whole with a glass of water and not cut, crushed or chewed approximately one hour before your cipagluco­sidase alfa infusion.

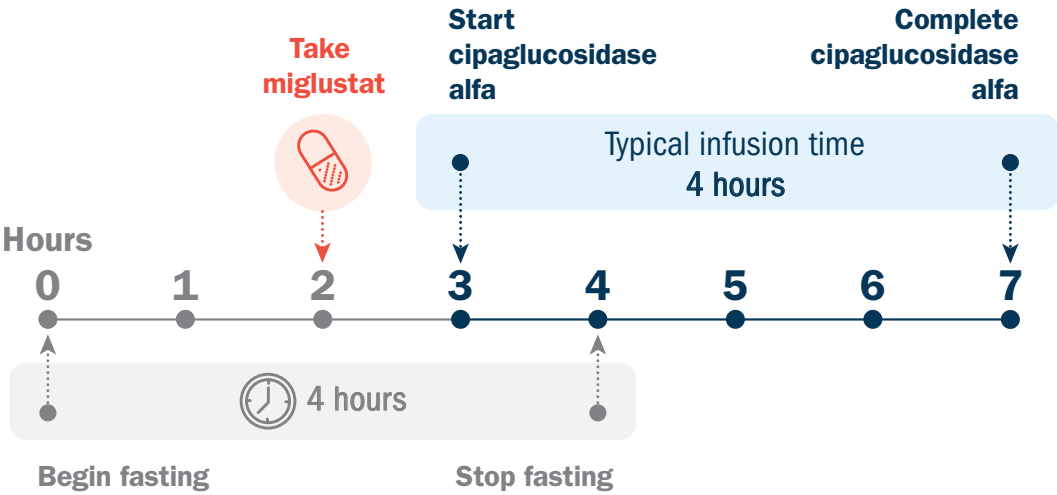
FASTING

- To ensure that miglustat (the stabiliser) works properly, it is very important that you fast for two hours before and two hours after taking miglustat, consuming no food for a total of four hours. You may only drink water, carbonated water, tea or coffee without milk or sugar.

INFUSION

- About an hour after taking the miglustat capsules, your cipagluco­sidase alfa infusion will start. Cipagluco­sidase alfa is given to you by a doctor or nurse. It is given through a drip into a vein in your arm or port. This is called an ‘intravenous infusion’.
- The infusion should take around four hours. The infusion rate will start off slowly and then increase gradually.
- Once all infusion has been administered, the tubing will be flushed to ensure it has all been given to you.
- Please speak to your healthcare professional team if you have any questions regarding your infusion.

Figure 1. Dosing timeline



HOW MUCH CIPAGLUCOSIDASE ALFA IS GIVEN?

- The amount of medicine that you will be given is based on your weight. The recommended dose is 20 mg for each kg of body weight.

WHEN IS CIPAGLUCOSIDASE ALFA GIVEN?

- You will be treated with cipagluco­sidase alfa once every other week.

WHAT TO DO IF YOU TAKE YOUR DOSE OF MIGLUSTAT AT THE WRONG TIME

- If you take your miglustat capsules at the wrong time, speak to your healthcare professional. The infusion can be delayed up to three hours from when you took your miglustat capsules.

WHAT TO DO IF YOU TAKE TOO MANY MIGLUSTAT CAPSULES

- If you accidentally take more capsules than you were prescribed, you may be at increased risk of experiencing side-effects with this medicine. Contact your healthcare professional immediately or go to the hospital.

WHAT TO DO IF YOU MISS A DOSE OF CIPAGLUCOSIDASE ALFA:

- If you may miss or have missed the time by which the infusion was supposed to be started, please speak to your healthcare professional immediately.

YOUR INFUSION DIARY FOR

cipaglucosidase alfa home infusion

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ADMINISTRATION DETAILS (TO BE COMPLETED BY TREATING PHYSICIAN)	
Date of first administration	
First infusion at home	

CIPAGLUCOSIDASE ALFA/MIGLUSTAT DOSING REGIMEN	
Miglustat dose	
Cipaglucosidase alfa dose	
Frequency	
Rate of infusion	
Required reconstituted volume (mL)	
Total volume in infusion bag (mL)	
Pre-treatment medication (if applicable)	
Reasons for cipaglucosidase alfa infusion at home	
Findings and actions from the initial interview	
Indicate support to be provided by infusion healthcare professional/ nurse at home	

NECESSARY ACTIONS IN THE EVENT OF A SEVERE INFUSION-ASSOCIATED REACTION OR HYPERSENSITIVITY REACTION

(TO BE COMPLETED BY TREATING PHYSICIAN)

1	STOP the infusion	
2	Call the emergency services	
3	Call your treating physician	
	Telephone number	
	Telephone number (24hr)	
	Name of physician	
	Name of clinic	
	Total volume in infusion bag (mL)	
	Address	
4	Emergency medication	
	Medication, including dose	
5	Patient's contact person to be notified	
	Name	
	Telephone	

COMPLETE THIS FORM FOR EVERY INFUSION SESSION

The patient and/or caregiver(s) have been informed about the associated risks of home infusion of cipagluco­sidase alfa, and proper education on the use of emergency medications has been provided. In the event of any infusion-associated reaction, the infusion must be immediately discontinued. Necessary actions in the event of a severe infusion-associated reaction, including emergency contact details, are described in this Infusion Diary. Keep this information readily available during the infusion procedure. To request additional copies of this infusion diary please email: info@amicusrx.co.uk or call: **01753 888 567**.

Date of first administration	
First infusion at home	
INFUSION SESSION	
Date of infusion	
Infusion healthcare professional/nurse	
Caregiver, if present	
DOSE	
Miglustat dose	
Time of miglustat dose	
Cipagluco­sidase alfa dose	
Patient weight (kg)	
Cipagluco­sidase alfa batch/lot number	
Time of cipagluco­sidase alfa infusion start	
Required reconstituted volume (mL)	
Number of vials used	
Duration of infusion	
Rate(s) of infusion	
Problems/Remarks related to the infusion, if any (including infusion- associated reaction(s), action taken, and outcome):	
Indicate support to be provided by infusion healthcare professional/nurse at home:	

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Rate(s) of infusion	
Problems/Remarks related to the infusion, if any (including infusion- associated reaction(s), action taken, and outcome):	
Indicate support to be provided by infusion healthcare professional/nurse at home:	

COMPLETE THIS FORM FOR EVERY INFUSION SESSION

The patient and/or caregiver(s) have been informed about the associated risks of home infusion of cipagluco­sidase alfa, and proper education on the use of emergency medications has been provided. In the event of any infusion-associated reaction, the infusion must be immediately discontinued. Necessary actions in the event of a severe infusion-associated reaction, including emergency contact details, are described in this Infusion Diary. Keep this information readily available during the infusion procedure. To request additional copies of this infusion diary please email: info@amicusrx.co.uk or call: **01753 888 567**.

Date of first administration	
First infusion at home	

INFUSION SESSION	
Date of infusion	
Infusion healthcare professional/nurse	
Caregiver, if present	

DOSE	
Miglustat dose	
Time of miglustat dose	
Cipagluco­sidase alfa dose	
Patient weight (kg)	
Cipagluco­sidase alfa batch/lot number	
Time of cipagluco­sidase alfa infusion start	
Required reconstituted volume (mL)	
Number of vials used	
Duration of infusion	
Rate(s) of infusion	
Problems/Remarks related to the infusion, if any (including infusion- associated reaction(s), action taken, and outcome):	
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