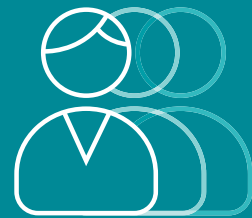


Replagal[®]

[agalsidase alfa]



Patient/Caregiver/HCP Guide for Self-administration/Home Infusion of Replagal[®]

This Guide is intended for patients who have been prescribed Replagal[®], and their caregivers and healthcare professionals (HCPs) who may assist them with self-administration/home infusion. Please read this Guide thoroughly and carefully before using this medicine as it contains important information for you.

Contents

01 What is this Guide for?	5	10 Disposal of waste material	21
02 My information	6	11 What to do if side effects occur with Replagal®	22
03 What is Replagal®?	7	Possible side effects of Replagal®	22
What will treatment look like?	7	Other problems that might occur with Replagal® self-administration	22
How long will I be on treatment?	7	Report any side effects or problems	22
04 Important things to remember	8	12 Infusion diary	23
05 Handwashing: good technique	10	13 For administration of Replagal®	24
06 Preparation for Replagal® self-administration	11	Your recommended dose	25
Before you begin	11	Track your infusion schedule	25
Things you'll need	12	14 Infusion diary entries	26
Check the Replagal® vial(s)	14		
Set up your work area	15		
Prepare the infusion site	15		
07 Prepare the infusion	16		
Prepare the solution	16		
Connect the infusion line	17		
08 Administer the Replagal® infusion	18		
Follow your doctor or nurse's instructions for infusing Replagal®	18		
Infusion starts here	18		
After the infusion	19		
09 Complete your infusion diary	20		

Replagal®

[agalsidase alfa]

This Guide is not a substitute for any additional training materials you may have received from your treatment clinic or the Replagal® Patient Information Leaflet. Please read the Patient Information Leaflet carefully.

- Keep this Guide. You may need to reread it, and it contains your Infusion Diary, which you will need to fill in after each infusion. You must always bring your Infusion Diary to each appointment with your treatment team.
- Ask your doctor or another healthcare professional who assists or supports you if you have any further questions.
- Talk to your doctor or healthcare professional if you experience any side effects. This includes any possible side effects, even if not listed in this Guide.

Abbreviations

EXP	Expiry
HCP	Healthcare Professional
IV	Intravenous (into a vein)
mg	Milligram
mL	Mililitre

What is this Guide for?

You have received this Guide because your treating physician has prescribed you Replagal® as a treatment for Fabry Disease. If your initial infusions of Replagal® in the clinic have gone well, you may be able to self-administer your infusions at home, to make things easier for you.

Depending on your situation, you may be allowed to infuse the medicine yourself (self-administer) at home after you or your caregiver have been appropriately trained. This Guide is designed to help you or your caregiver self-administer Replagal® at home.

Please note that the instructions in this Guide assume that you are infusing Replagal® using a standard IV (intravenous; 'into the vein') drip. However, you may receive Replagal® differently, for example, using an infusion pump. Please follow your treatment clinic's instructions and training in either case.

This Guide is intended to:

- ✓ Remember, when self-administering Replagal® at home, you must always have a caregiver or responsible adult with you. This person should be able to get in touch with your doctor or the local hospital if needed.
- ✓ Train you on the correct preparation and administration techniques, including:
 - How to reduce the risk of infection by using 'aseptic technique' (a collection of medical practices and procedures that helps protect patients from dangerous germs) before self-administering Replagal® at home.
 - How to insert and secure an IV needle set into your vein. Please make sure that your healthcare professional has trained you on this and that you are confident with the steps and the technique before trying it yourself at home.
- ✓ Reinforce that you must use the dose and infusion rate your doctor prescribed when self-administering Replagal® at home and that you must not change these unless your doctor tells you to do so.

- ✓ Reinforce that you need to have any medicines your doctor has prescribed at your disposal that will help reduce the risk or manage any reactions related to the infusion that might occur. You should know what these medicines are for and when and how to use them.
- ✓ Educate you on the signs and symptoms of potential reactions related to your infusion and other side effects associated with Replagal®, and know what to do if these happen.
- ✓ Remind you that it is essential to write down the details of each infusion in your Infusion Diary, including details of any reactions or side effects. This Guide includes your Infusion Diary. You need to keep it safe and always take it to your medical appointments so you can discuss it with your doctor or treatment team.

Your treating physician will decide whether you can choose to self-administer Replagal® at home. Do not start self-administration of Replagal® at home until you have received complete instructions and agreement to do so from your treatment clinic.

Please note that the instructions in this Guide assume that you are infusing Replagal® using a standard IV drip. However, you may receive Replagal® differently, for example, using an infusion pump. Please follow your treatment clinic's instructions and training in either case.

Please remember that keeping an up-to-date record of Replagal® treatments in your Infusion Diary is very important. It allows your doctor to better monitor your treatment and any issues that may occur.

My information

Be sure to record emergency/out-of-hours contact details here in case you should experience issues while on Replagal® treatment at home and need help.

Name	
Phone number	
Doctor	
Doctor's phone number	
Doctor's email	
Treatment clinic	
Emergency/out-of-hours contact phone number	
Additional information	

Notes:

What is Replagal®?

The active substance in Replagal® is agalsidase alfa (1 mg/mL). Agalsidase alfa is a human enzyme (a type of protein) produced by 'switching on' the gene for making this enzyme in human cells. The enzyme is then removed from the cells and made into Replagal®.

Replagal® is used to treat adult patients, as well as adolescents and children from the age of seven (7 years), with a confirmed diagnosis of Fabry Disease. It is used as long-term enzyme replacement therapy when the level of the enzyme (agalsidase alfa) in the body is absent or lower than normal, as in Fabry Disease.

After six (6) months of therapy, Replagal® has been shown to significantly reduce pain in patients when compared to patients treated with placebo (dummy medication). Replagal® has also been shown to reduce over-bulky heart muscle size in Replagal®-treated patients compared to placebo-treated patients. These results suggest that the symptoms of the disease are improving and/or the disease is becoming stable.

What will treatment look like?

Replagal® is a liquid medication given through infusions into a vein once every two weeks. Each infusion should take about 40 minutes.

How long will I be on treatment?

Fabry Disease is a chronic condition that can be treated throughout your life. Replagal® is used for long-term enzyme replacement therapy in patients with a confirmed diagnosis of Fabry Disease. It is essential to follow your doctor's instructions and stay on track with Replagal® infusions.

Notes:

Important things to remember about Replagal® treatment

Do

- ✓ Ensure a caregiver or responsible adult is present when you self-administer a Replagal® infusion at home. This person should be ready to contact your doctor or nearest hospital if needed (see the “What to do if side effects occur with Replagal®” section of this leaflet, which outlines what to do if you feel unwell during/after your infusion).
- ✓ Always use Replagal® precisely as your doctor has instructed. You must follow the prescribed dosing and infusion rate.
- ✓ Have any medicines your doctor has prescribed to help with reactions related to the infusion to hand.
- ✓ Remind yourself or your caregiver of the signs and symptoms of reactions related to the infusion and other side effects of Replagal®. Refer to the Patient Information Leaflet and the “What to do if side effects occur with Replagal®” section in this leaflet. You or your caregiver should report any side effects you get (see the section on “What to do if side effects occur with Replagal®”).
- ✓ Follow the instructions about how soon to remove Replagal® from the refrigerator before your infusion.
- ✓ Keep your work area and equipment clean when infusing Replagal® at home.
- ✓ Be hydrated by drinking enough water before starting your infusion.
- ✓ Insert the butterfly, cannula, or infusion port needle before preparing the solution for infusion, as per your doctor’s instructions.
- ✓ Try to ensure that you are not interrupted whilst infusing and that there are no distractions.
- ✓ Ideally, administer the infusion during daytime hours so that you can quickly obtain help or advice if needed.
- ✓ **Stop the infusion and contact your treatment clinic immediately** if you are self-administering Replagal® and experience side effects associated with the infusion.
- ✓ Fill in your Infusion Diary, which is included in this Guide – this is important for helping your doctor keep track of your treatment.
- ✓ Continue your infusions once every 14 days unless your treating physician has instructed you to stop them.
- ✓ Store Replagal® in a refrigerator and monitor the refrigerator temperature to ensure that Replagal® remains in the 2-8°C range. Contact your treatment clinic for advice if the temperature falls below this range.
- ✓ Keep Replagal® out of sight and reach of children.

Notes:



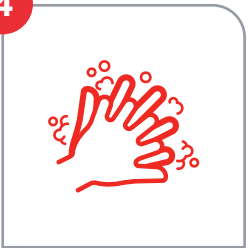


Do not

- ✗ **DO NOT** use Replagal® if you feel unwell. Seek advice from your treatment clinic.
- ✗ **DO NOT** use Replagal® at home if you do not have a caregiver or responsible adult with you.
- ✗ **DO NOT** change the dose of Replagal® or the infusion rate unless your treating physician has told you to do so.
- ✗ **DO NOT** begin self-administration of Replagal® at home until you have received complete instructions from your treating physician/treating team and have understood these.
- ✗ **DO NOT** use Replagal® if you are allergic to agalsidase alfa or any other ingredients of this medicine (please refer to the Replagal® Patient Information Leaflet).
- ✗ **DO NOT** use Replagal® after the expiry date stated on the label and the carton (see ‘EXP’). The expiry date refers to the last day of that month.
- ✗ **DO NOT** use Replagal® if you notice damage to, or evidence of tampering with, the packaging or if the medicine is discoloured or contains visible particles (‘bits’ in the solution).
- ✗ **DO NOT** infuse Replagal® in the same IV line/infusion set together with other fluids/medicine.
- ✗ **DO NOT** throw away any medicines via wastewater or household waste.
- ✗ **DO NOT** forget to fill in your Infusion Diary.

Notes:

Handwashing: good technique

Instructions later in this Guide recommend that you wash your hands; the steps below describe the appropriate handwashing technique. Please ensure that your sink and sink area are clean before washing your hands.

- 1  Wet hands with water.
- 2  Apply enough soap to cover all hand surfaces.
- 3  Rub hands palm to palm.
- 4  Rub the back of each hand with the palm of the other hand with fingers interlaced.
- 5  Rub palm to palm with fingers interlaced.
- 6  Rub with the back of your fingers to opposing palms with fingers interlocked.
- 7  Rub each thumb clasped in the opposite hand using a rotational movement.
- 8  Rub tips of fingers in the opposite palm in a circular motion.
- 9  Rub each wrist with the opposite hand.
- 10  Rinse hands with water.
- 11  Dry thoroughly with a single-use towel.
- 12  Handwashing should take between 30 seconds and 1 minute.

Notes:

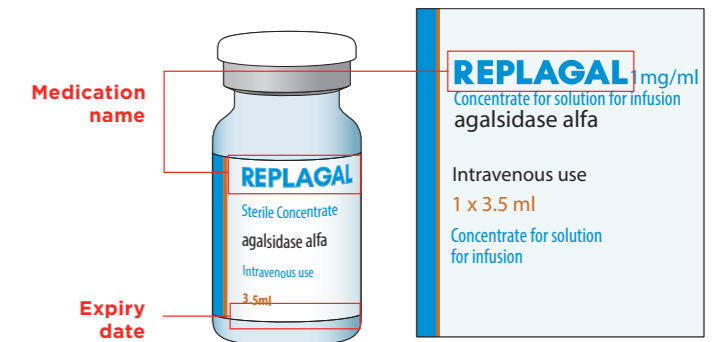
Preparation for Replagal® self-administration

Before you begin

Reminder: Please make sure the treatment clinic team gives you copies of this Guide, which should include an Infusion Diary within it.

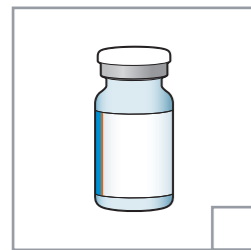
- Decide on a time and place to infuse Replagal® with your caregiver or responsible adult who will be there when you self-administer. Ideally, this will be in a quiet area with no distractions and during daytime hours so that you can quickly obtain help or advice if needed
- Make sure you or your caregiver know and understand the side effects you could get with Replagal® and what to do if they occur. Make sure you have access to your phone in case you or your caregiver need to call your treatment clinic, physician or hospital.
- Ensure you have everything you need (see the section entitled 'Get ready'). This might include additional medication from your doctor to prevent, mitigate or manage reactions related to the infusion.
- Follow your doctor's instructions about how soon to remove Replagal® from the refrigerator before your infusion.

Notes:

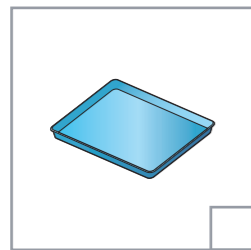


Things you'll need

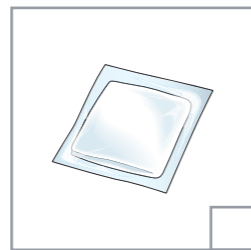
Your treatment team will provide the items you will need for your infusion. **Examples of these are shown here, but the items you receive may vary in appearance or colour.** Tick boxes are included to the right, so your treatment team can indicate the items you need.



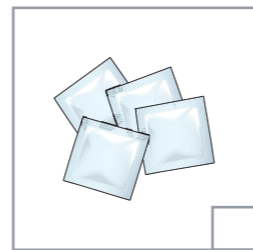
Replagal® vial(s)



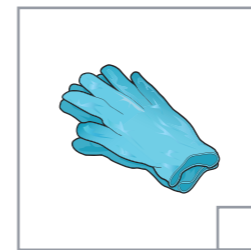
Medical tray



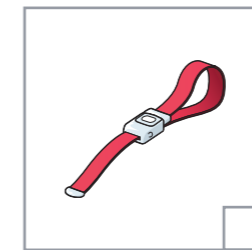
Dressing pack/sterile drape



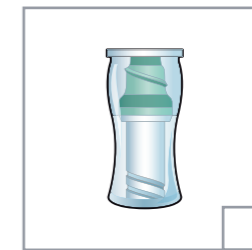
Alcohol wipes



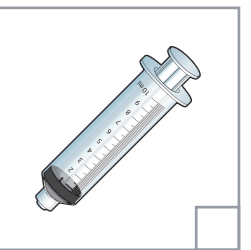
Gloves



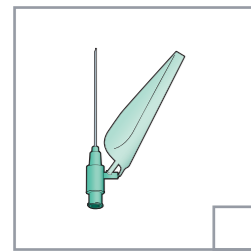
Tourniquet



Needle-free bung



10 mL syringes



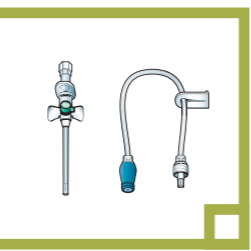
21G green safety needles

An infusion set



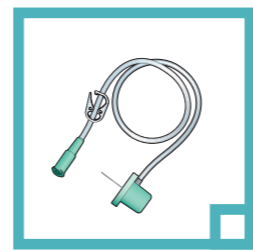
Butterfly

OR

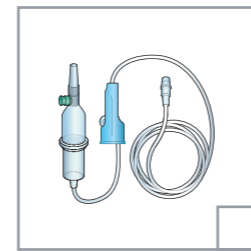


Cannula with extension

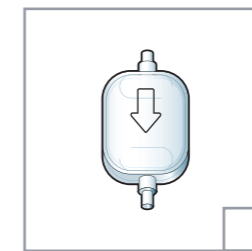
OR



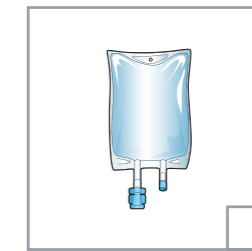
Infusion port needle (port-a-cath needle)



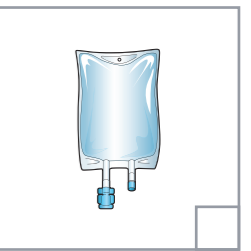
Giving set



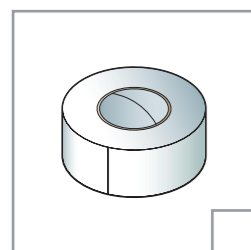
Filter



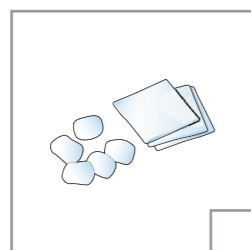
0.9% sodium chloride (saline) infusion bag (100 mL)



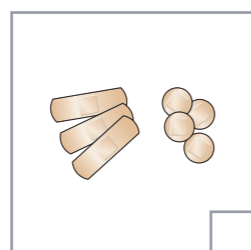
0.9% sodium chloride (saline) flush bag (as prescribed)



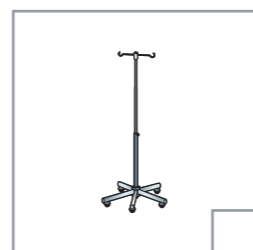
Tape



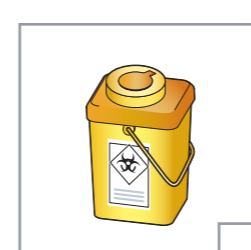
Cotton balls/gauze



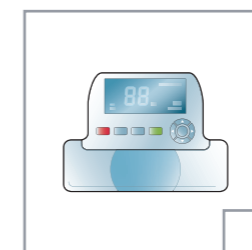
Plasters



Drip stand



Sharps container



Infusion pump

Please note: If you use an infusion pump to deliver your infusions, follow the instructions given to you by your treatment clinic instead of following all the instructions in this Guide.

Notes:

Notes:

Check the Replagal® vial(s)

- Make sure you have the correct number of Replagal® vials.
- DO NOT use them if the protective caps are missing or broken.
- Check that the details on the box and pharmacy label are correct. If any details are incorrect, DO NOT use your medication and contact your treatment clinic immediately.
 - ✓ Check that the medication is intended for you.
 - ✓ Check that the name of your medication (Replagal®) is correct.
 - ✓ Check that the medication has not gone past its expiry date.
- DO NOT use the medication if the expiry date has passed.
- Check the packaging for evidence of damage or tampering, and check the vial(s) for discolouration or visible particles ('bits' in the solution).

If the liquid is not clear and colourless, or there is evidence of damage/tampering, DO NOT use the medication and contact your treatment clinic immediately.

- Let the vial(s) of Replagal® warm up to room temperature.
- DO NOT try to heat the solution in the microwave, by placing the vials in hot water, or by applying heat in any other way.



If Replagal® is unusable because the expiry date has passed, the solution doesn't look right, or the caps of the vials are missing or broken, contact your treatment centre.

Please DO NOT dispose of any unsuitable Replagal® as it will need to be examined by the manufacturer to discover the reason for any fault.

Set up your work area

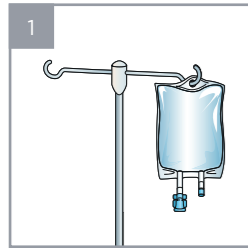
- Prepare a clean, flat surface and gather all the materials you need for the infusion.
- If your doctor has prescribed an adrenaline/epinephrine pen or other supportive care for certain severe allergic symptoms, keep it nearby during your infusion. Carefully follow your doctor's instructions and training if you have to administer the prescribed medicine for a severe allergic reaction.
- Wash your hands and allow them to dry (you can follow the instructions above).
- Apply gloves as directed by your healthcare professional.
- Open supplies as shown by your healthcare professional.

Prepare the infusion site

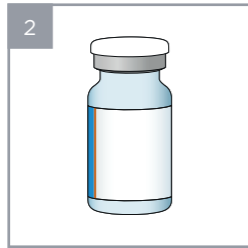
- Select an infusion site as directed by your treating physician or a team member in the clinic. Please ensure you rotate infusion sites (insert the needle/cannula in different sites/areas with each infusion).
- Apply a tourniquet and prepare the infusion site by wiping the skin well with an alcohol swab (or other suitable solution suggested by your healthcare provider) and wait for the skin to dry.
- Your treatment team will show you/caregiver/HCP in the home how to prepare a flush syringe (~10 mL) filled with 5-10 mL of normal saline. Once the saline flush syringe has been prepared, tap the nozzle while the syringe is upright to remove excess air and air bubbles. Place this syringe to one side in your clean work area.
- Insert and secure the IV needle set (a butterfly, cannula or infusion port needle) with tape or a dressing, as instructed by your treating physician (or a member of the treating team) in the clinic.
- Release the tourniquet, attach the saline flush syringe to the IV needle set and flush the IV needle set through with 5-10 mL of normal saline (0.9% NaCl [sodium chloride] solution) to check if the needle placement is correct. Your treating physician or a clinic team member will have shown you how to do this correctly. If not successful, repeat steps as directed by your treating physician or treatment team.
- Remove the saline flush syringe before attaching the IV infusion set filled with Replagal® solution.

Prepare the infusion

Prepare the solution

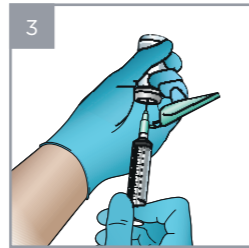


1 Remove the outer wrapper of the infusion bag (100 mL 0.9% Sodium Chloride [saline] for solution) and hang the bag on the drip stand.

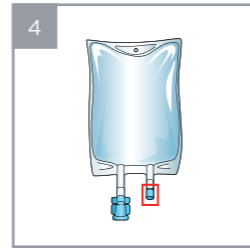


2 For each Replagal® vial you need to:

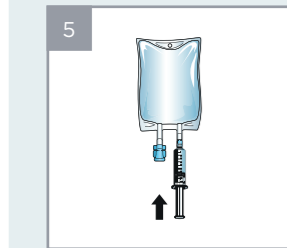
- Remove the cap.
- Wipe the rubber stopper with an alcohol wipe.
- Allow it to dry for 30 seconds.



3 Connect a safety needle to a sterile syringe. While avoiding contact with the syringe needle or vial cap, draw the Replagal® from the vial(s) into the syringe. Repeat this step for each vial required for your infusion (as prescribed).

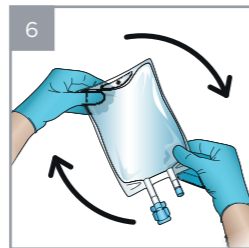


4 Wipe the injection port on the infusion bag (**port A**) with an alcohol wipe and allow it to dry for 30 seconds.

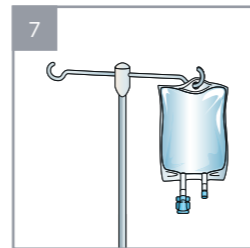


5 Remove the needle from the syringe and dispose of the needle in the sharps bin, screw the syringe into **port A**, and inject all the Replagal® into the infusion bag. Then, remove the syringe and dispose of it in the sharps bin. Never put the cap back onto the needle.

Please note: If your treating physician or treatment team has instructed you to inject the Replagal® into the infusion bag using a needle, skip step 5 and follow the instructions from your treating physician or treatment team. Dispose of the needle in the sharps bin once you have injected the Replagal® into the infusion bag.



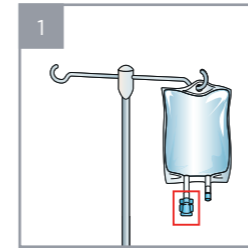
6 Remove the bag from the drip stand and gently turn the infusion bag to ensure that the Replagal® mixes thoroughly in the solution, but **DO NOT** shake the bag.



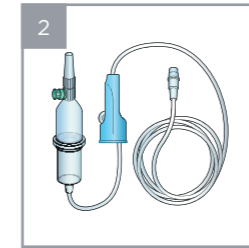
7 Hang the bag on the drip stand and check the liquid for discoloration and particles. **DO NOT** use if the solution is discoloured or visible particles ('bits') are present. Instead, contact your treatment clinic immediately.

Note: The administration should begin as soon as possible after dilution.

Connect the infusion line

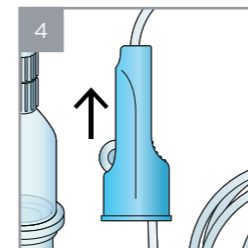


1 Twist off the large cap attached to the infusion port on the infusion bag (**port B**).

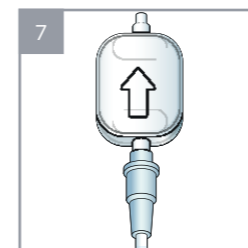


2 Open the giving set, and unravel the tubing, holding onto both ends. **DO NOT** allow either end to fall to the floor or come into contact with any other surface.

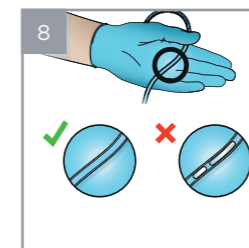
An IV giving set (see 'Things you'll need'), or drip giving set, is one of the most common medical devices used to administer intravenous fluids directly into a patient's vein.



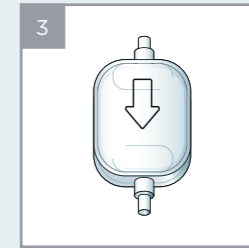
4 Use the roller clamp to clamp the tube, as instructed by your healthcare professional. The clamp should be closed.



7 'Prime' the tube by opening the roller clamp very slowly, allowing fluid to pass slowly along the tube until it reaches the end.

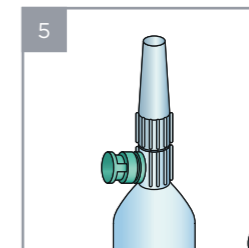


8 Make sure there are no bubbles in the tube - you can hold the free end upright and gently 'flick' the tube to allow the bubbles out.

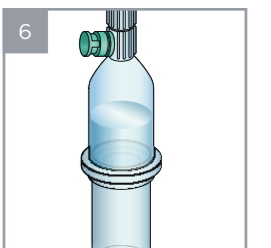


3 Connect the filter to the giving set (at the end without the 'spike' and with the arrow pointing in the direction of flow - towards the patient).

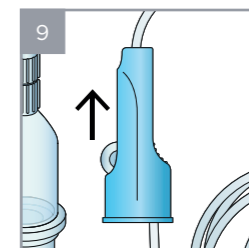
Please note: If your giving set has the filter pre-installed, then please skip step 3.



5 Remove the cap from the 'spike' at one end of the tube and insert it into **port B** using a twisting motion.



6 Squeeze the drip chamber until it fills halfway with fluid.



9 Finally, close the roller clamp.

If you use an infusion pump, your treating physician or treatment team will show you how to prime your infusion line.

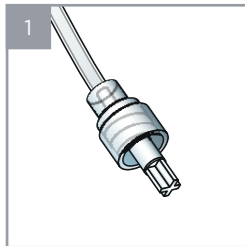
Administer the Replagal® infusion

If you are using an infusion pump, please follow the guidance given to you by your healthcare professional.

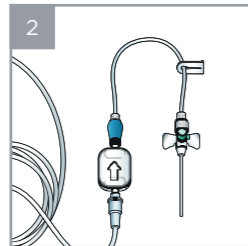
Please note: If a gloved hand becomes contaminated during the procedure shown below:

- Remove your gloves and dispose of them.
- Wash your hands using the appropriate handwashing technique.
- Apply a new pair of gloves.

Follow your healthcare professional's instructions for infusing Replagal®



Use an alcohol wipe to carefully wipe the connector of the cannula extension (shown here), butterfly needle, or infusion port needle, and allow to dry for 30 seconds.

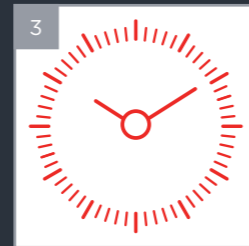


If your giving set does not have a filter pre-installed: Remove the cap from the end of the filter and connect the filter to the cannula extension (shown here), butterfly needle, or infusion port needle.

OR

If your giving set has a filter pre-installed: Connect the end of the giving set to the cannula extension (shown here), butterfly needle, or infusion port needle.

Infusion starts here



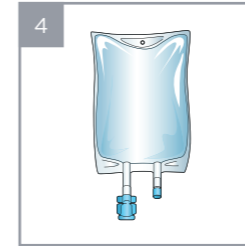
Open the roller clamp and administer Replagal® solution at room temperature at a rate as directed by your healthcare professional.

The infusion should take approximately 40 minutes, and you can adjust the drip rate using the roller clamp:

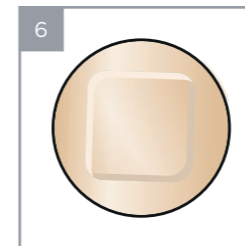
- The total infusion volume is about 100 mL, and 1 mL is about 20 drips.
- For a 40-minute infusion, the drip rate will be about 50 drips per minute.

Check the infusion site occasionally throughout the infusion.

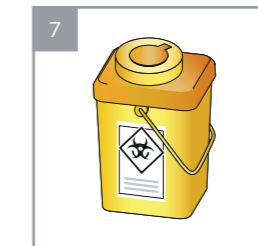
After the infusion



At the end of the infusion, ensure that the roller clamp is closed, then remove your infusion bag and attach a flush bag (see 'Things you'll need') as demonstrated by your healthcare professional. This ensures you receive all the Replagal®, including any left in the giving set. Once the flush bag is attached, open the roller clamp, allow some of the saline from the flush bag to infuse as instructed by your treating physician or treatment team, and then close the roller clamp.

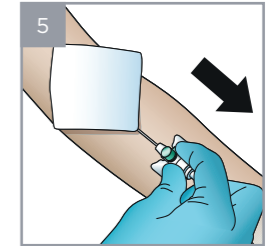


Check that bleeding has stopped before applying a plaster. If the exit site continues to bleed after 5 minutes, re-apply firm pressure.



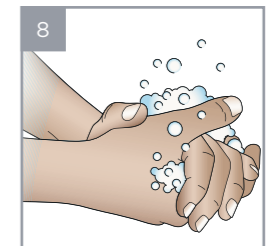
After the infusion, dispose of sharps (needles or cannula) in the sharps bin. Remove the stickers (showing expiry date and batch number) from the Replagal® vials and stick them to your diary sheet (or write this information in the Infusion Diary). Then put the vials in the sharps bin also. Use the partial lock to close your sharps bin. Put all other packaging in the household refuse or recycling bin.

DO NOT throw away any medicines via wastewater or household waste. Dispose of the remaining contents of any opened vials in the sharps bin.



Place gauze over the needle site and slowly withdraw the needle/cannula, putting it in the sharps bin. Apply firm pressure to the exit site for around 3 minutes.

DO NOT recap the IV needle set.



Remove your gloves and dispose of them. Wash your hands using the appropriate hand hygiene technique (see 'Handwashing: Good technique'). Always clean your tray or work surface with warm soapy water, and rinse and dry after use.

Complete your Infusion Diary

Please note: At the end of the infusion, record each treatment infusion and any issues you may have had in your Infusion Diary

- At the end of your infusion, write down the following in your Infusion Diary:
 - Date and time (start and end) and note any interruptions.
 - Dose and site of infusion (to assist in rotating infusion sites).
 - Any side effects during or after each infusion.
 - Place the stickers from your vials (if available on the vial), showing the expiry date and batch/lot number, in the indicated 'Batch/lot number and expiry date' area (alternatively, write this information in this area).
- Repeat this for each infusion.
- Start a new sheet when you run out of room on the sheet. When you are on your last remaining Infusion Diary sheets, ask your treatment clinic to provide a new Patient Guide (which includes an Infusion Diary).
- Report all side effects to your doctor.
- Keep each Infusion Diary for at least a year.

Notes:

Disposal of waste material

Any unused medicinal product or waste material should be disposed of following local requirements.

If you have been asked to dispose of waste infusion products in a sharps container, important points to remember include:

- Always ensure the lid is securely fastened to the body of the sharps container.
- Always store the closed sharps container out of reach and sight of children and vulnerable adults.
- Do not overfill your sharps container.
- Always keep your sharps container upright.
- Never put your hand into the sharps container to retrieve a dropped item.



Notes:

14
Infusion Diary entry

Step 1
Before you begin

Refer to your Patient Guide, the Patient Information Leaflet, and the training you have received from your training organisation to ensure you are able to set up and carry out your infusion and what signs and symptoms to look out for during and after your infusion.

Tick box if caregiver present

Date of infusion: _____
Your weight: _____
Dose: _____
Route: _____
Medicine (type, dose, colour): _____
List any additional medication taken before your infusion: _____

Notes:
What you felt during your infusion.
Questions for your healthcare team

Step 2
Infusion

Which arm will you infuse into?
 Left Right

Which infusion site are you using?
 [Diagram of arm] [Diagram of hand]

Start time: _____
Stop time: _____
Approximate infusion time (minutes): _____

Review this infusion with your doctor.
Please report side effects directly. Physiological signs of severe toxicity. Abnormalities, adverse events and/or symptoms (e.g. rash, fever, chills, dizziness, headache, nausea, vomiting, diarrhoea, hypotension, tachycardia, etc.) or any other symptoms.

Step 3
Stick or record vial labels

Record the product batch/lot number, vial size, and expiry date from each 'Receptal'™ vial used below.

Lot/Serial number Vial size Expiry date	Lot/Serial number Vial size Expiry date
Lot/Serial number Vial size Expiry date	Lot/Serial number Vial size Expiry date
Lot/Serial number Vial size Expiry date	Lot/Serial number Vial size Expiry date
Lot/Serial number Vial size Expiry date	Lot/Serial number Vial size Expiry date
Lot/Serial number Vial size Expiry date	Lot/Serial number Vial size Expiry date
Lot/Serial number Vial size Expiry date	Lot/Serial number Vial size Expiry date
Lot/Serial number Vial size Expiry date	Lot/Serial number Vial size Expiry date
Lot/Serial number Vial size Expiry date	Lot/Serial number Vial size Expiry date

Copyright 2022 Takeda Pharmaceutical Company Limited. All rights reserved.

What to do if side effects occur with Replagal®

Side effects due to reactions related to the infusion and errors related to how the medication is taken/given may occur in association with self-administration of Replagal®.

Although rare, hypersensitivity reactions can occur. The most frequently reported symptoms of hypersensitivity include nausea, rash, difficulty breathing, back pain, chest discomfort or tightness, hives, pain in the joints, and headache. You should notify your treating physician immediately if this happens, and subsequent testing for agalsidase alfa antibodies is advised should you experience a reaction suggestive of hypersensitivity. Your treating physician may decide that your subsequent infusions must occur in the hospital.

Possible side effects of Replagal®

You may be allergic to Replagal®, even if you have had medicines like Replagal® before and tolerated it/them well. In some cases, severe allergic reactions may occur.

Your doctor will tell you about signs and symptoms that may occur and that you need to let your doctor know about immediately. These signs and symptoms may include:

- Chills, flushing, faster heartbeat, fall in blood pressure, light-headedness, rash, hives, itching, difficulty breathing or swallowing, and swelling of your hands, face, or mouth.

Life-threatening allergic reactions ('anaphylactoid reactions') have been reported in some patients. If the reaction is serious, your doctor or healthcare professional may decide whether to slow or stop the infusion completely, and they may start treatment for the allergic reaction.

Tell your healthcare professional immediately if you notice such reactions during the infusion.

In case of self-administration at home, stop the infusion immediately and contact your healthcare professional.

Other issues that might occur with Replagal® self-administration

Make sure you discuss the possibility of problems arising while self-administering Replagal® treatment at home with your treating physician.

Problems that might occur while you are self-administering Replagal® at home include, but are not limited to:

- Equipment that is either not the right equipment, doesn't work correctly or fails.
- Not giving Replagal® correctly (e.g. mechanical or medication errors).
- Skin or tissue reactions where you insert the needle (or cannula), including redness, pain, swelling, bruising, bleeding, and infection.
- Allergic reactions (see description of symptoms and signs above).
- Slowed or stopped Replagal® infusion flow rate.
- Air embolism (air bubbles released into the bloodstream).

Report any side effects or problems

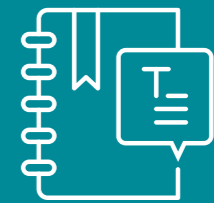
These are not all the possible side effects or problems. Tell your doctor about any side effect that bothers you or does not go away, problems with self-administering Replagal® treatment at home, or if you suspect your treatment isn't working as it should.

You are also encouraged to report negative side effects or problems with prescription drugs to HPRA Pharmacovigilance at www.hpra.ie. Alternatively, adverse events should be reported to Takeda Products Ireland Ltd on 1800 937 970 (freephone from Ireland only) or +44 (0)3333 000181 or via AE.GBR-IRL@takeda.com.

When reporting, please provide as much information as possible, including describing any side effects or problems and interventions/treatments for those, the medication taken, dates and timings, other medication and health issues, etc.

Replagal®

[agalsidase alfa]



Infusion Diary

This Infusion Diary is intended for patients who have been prescribed Replagal®. It is intended for use alongside the Replagal® Patient Guide, and Patient Information Leaflet or package insert.

Keep this treatment diary for a year after it has been completed. You may need to refer back to it.

If you have any further questions, ask your doctor or healthcare professional.

Talk to your doctor or healthcare professional if you experience any side effects.

For administration of Replagal®

If self-administration is considered appropriate for you, ensure that you receive detailed instructions and adequate training from your healthcare professional/s on how to self-administer at home or in another appropriate setting and that you have demonstrated the ability to administer Replagal® independently.

This infusion diary belongs to:

Name		
Phone number		
For infusions from (date)	to	

Key contacts

Doctor	
Nurse	
Pharmacy	
Caregiver	
Emergency /out-of-hours contact	

Your recommended dose

Important: Your doctor will calculate the Replagal® dose for you and help you fill in this section on dose and recommended infusion rate. Do not attempt to calculate or alter the dose yourself.

Date	
Your weight	
Dose	
Number of Replagal® vials required	
Recommended infusion time (minutes)	
Additional information	

Track your infusion schedule

Recording infusions is an important step to help you stay on track with your prescribed treatment plan. Tracking infusions helps maintain a routine around the regular infusion schedule and informs the healthcare team of any questions or concerns you may have.

Be sure to capture any notes you may have about your treatment for your healthcare team. You must always bring this Infusion Diary to your appointments with your doctor to help discuss and understand your treatment experience.

Please remember that keeping an up-to-date record of the Replagal® treatments in your Infusion Diary is important.

Step 1

Before you begin

Refer to your Patient Guide, the Patient Information Leaflet, and the training you have received from your treating physician to remind yourself how to set up and carry out your infusion and what signs and symptoms to look out for during and after your infusion.

Tick box if caregiver present

Date of infusion	
Your weight	
Dose	
Needle (type/size/colour)	
List any additional medication taken before your infusion	

Notes:

How you felt during your infusion
Questions for your healthcare team

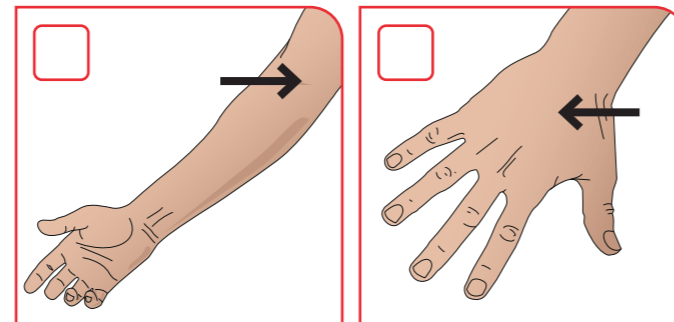
Step 2

Infusion

Which arm will you infuse into?

Left Right

Which infusion site are you using?



Inside elbow

Back of hand

If possible, do not use the same infusion site every time.

Start time	Hour	Min
Stop time	Hour	Min
Approximate infusion time (minutes)		

Review this infusion with my doctor

Please report side effects directly via HPRA Pharmacovigilance at www.hpra.ie.
Alternatively, adverse events should be reported to Takeda Products Ireland Ltd on 1800 937 970 (freephone from Ireland only) or +44 (0)3333 000181 or via AE.GBR-IRL@takeda.com.

If you experience any infusion-related side effects that persist or worsen, stop the infusion and contact your doctor immediately.

Step 3

Stick or record vial labels

Record the product batch/lot number, vial size, and expiry date from each Replagal® vial used below.

Lot/batch number:		Lot/batch number:	
Vial size:		Vial size:	
Expiry date:		Expiry date:	
Lot/batch number:		Lot/batch number:	
Vial size:		Vial size:	
Expiry date:		Expiry date:	
Lot/batch number:		Lot/batch number:	
Vial size:		Vial size:	
Expiry date:		Expiry date:	
Lot/batch number:		Lot/batch number:	
Vial size:		Vial size:	
Expiry date:		Expiry date:	
Lot/batch number:		Lot/batch number:	
Vial size:		Vial size:	
Expiry date:		Expiry date:	

