Cerezyme®
imiglucerase

CEREZYME® 400 AT HOME: A GUIDE FOR PATIENTS WITH GAUCHER DISEASE WHO ARE PRESCRIBED AND RECEIVE HOME INFUSION OF CEREZYME® 400

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 doctor.
- 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 should immediately notify your treating doctor or nurse.

South Africa/Namibia **Version 1: June 2024**

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1. YOUR DISEASE, TREATMENT AND HOME INFUSION

Together with your treating doctor, you have decided to start home infusion therapy with CEREZYME®. The objective of this document is to provide you with guidance on how to receive CEREZYME® at home.

GAUCHER DISEASE AND TREATMENT

People with Gaucher disease have low levels of an enzyme called acid ß-glucocerebrosidase. This enzyme helps the body to control the levels of glucocerebroside. Glucocerebroside is a natural substance in the body, made of sugar and fat. In Gaucher disease glucocerebroside levels can get too high inside specific cells called macrophages. When this happens, the cells are called "Gaucher cells". These large cells are mainly present in the bone marrow and organs like the spleen and the liver and can lead to disrupted function causing low number of blood cells, enlarged liver and spleen, and weaker bones. The presenting symptoms of Gaucher disease include pain in the bones and easy bruising or bleeding. Often the spleen and the liver are enlarged.

CEREZYME® is an artificial enzyme called imiglucerase. This can replace the natural enzyme acid β-glucocerebrosidase, which is lacking or not active enough in patients with Gaucher disease. CEREZYME® is used to treat patients who have a confirmed diagnosis of Type 1 or Type 3 Gaucher disease, who show signs of the disease.

Refer to the approved Patient Information Leaflet of CEREZYME® for additional information.

HOME INFUSION

The decision to receive home treatment should be made by you and your treating doctor after several months of hospital treatment to ensure satisfactory tolerance of the infusions.

A home care nurse, with the appropriate training provided by your treating doctor, will train and assist you and/or your caregiver in the beginning to ensure optimal treatment. However, should you prefer full support for your infusion at home, the home care nurse will carry out the entire procedure.

If you experience the following side effects with the treatment you must immediately stop the infusion and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to CEREZYME®. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Common side effects (occurring in more than 1 in 100 patients)

- Fever.
- Blue tinge to the nails, lips or face due to insufficient oxygen in the blood
- Abnormal fast heart rate
- Chest discomfort

These are all serious side effects. You may need urgent medical attention.

Tell your doctor as soon as possible if you notice any of the following:

Common (occurring in more than 1 in 100 patients):

- Dizziness, headache
- Flushing, low blood pressure
- Coughing
- Nausea, stomach pain, vomiting, diarrhoea
- Backache
- Unusual weakness or tiredness
- Chills (feelings of coldness, accompanied by shivering)

Uncommon (occurring in more than 1 in 1000 patients):

- Burning, swelling, sterile abscess at injection site

Not all side effects reported for CEREZYME® are included in this guide. Should your general health worsen or if you experience any untoward effects while receiving CEREZYME®, please consult your treating doctor immediately.

If side effects or infusion-associated reactions are experienced, subsequent infusions may need to occur in a clinical setting. The rate of the infusion and the dose while at home should follow the guidelines provided by your treating doctor, and not be changed without the agreement of your treating doctor and supervision of the home care nurse.

ORGANISATION

PATIENT

- You must be physically and mentally able to undergo the infusions at home. The treating doctor is responsible for recommending that you may receive CEREZYME® infusions at home.
- You and/or your caregiver must agree to receive the treatment at home.
- The home environment should 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 CEREZYME® and other infusion supplies.
- You have accessible blood veins that allow an infusion needle to be inserted. When you have a central venous access device you should be able to insert the infusion needle into the septum.
- You and/or your caregiver have been informed by the treating doctor 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 have an understanding of Gaucher disease, and are able to recognise side effects and understand the procedures to be followed should they occur.
- You and/or your caregiver have been adequately trained in the procedures of CEREZYME® reconstitution, dilution and infusion.

HOME CARE NURSE

- The home care nurse is qualified to give IV infusions.
- The home care nurse has been trained and instructed about CEREZYME® and is aware of the possible side effects and the actions to be taken should they occur.
- The home care nurse will establish with the patient and/or caregiver the level of support necessary.
- The home care nurse will have a coordinating task vis-à-vis the treating doctor and you and/or your caregiver in organising the treatment at home.
- The home care nurse will strictly follow the prescribed method of administering CEREZYME® as stated in the logbook.
- The home care nurse will record each administration of CEREZYME® in the logbook.
- In the event of a side effect occurring during or shortly after the infusion (i.e., infusion-associated reaction), the home care nurse/patient/caregiver should discontinue the infusion immediately and phone the treating doctor and/or the emergency number provided in the logbook.

TREATING DOCTOR

- The treating doctor is responsible for the training of the patient/caregiver
- The treating doctor is responsible for the appointment and ensuring adequate training of a home care nurse, where required
- The treating doctor is responsible for the initiation of all necessary administrative actions including training, allowing all stakeholders (pharmacy, nurse, patient, caregiver) to proceed.
- The treating doctor is responsible for the dose and the infusion rate. Any changes must be clearly communicated to the patient and described in the logbook.

THIRD PERSON/CAREGIVER

- It is preferable for a caregiver/third party to be present during home infusion.

THE LOGBOOK

- The logbook serves as a means of communication for everyone involved in administering CEREZYME® at home.
- The logbook should be kept at your home and will be kept up to date by you, your caregiver or the home care nurse.
- You and/or your caregiver and/or home care nurse will strictly follow the prescribed method of administration of CEREZYME® as stated in the logbook.
- You and/or your caregiver and/or home care nurse will record each administration of CEREZYME® in the logbook.
- You and/or your caregiver must take the logbook along to the hospital at each appointment for a check-up and bring it home afterwards.
- In the logbook, the treating doctor clearly states the dose and the infusion rate, as well as any changes.
- The home care nurse records all relevant information and actions from the initial interview and you, your caregiver or the home care nurse notes all relevant information from subsequent visits in the logbook.
- In the logbook, the treating doctor clearly states what has to be done and administered in the event of an infusion side effect.

PHARMACY AND INFUSION EQUIPMENT

- Treatment and all necessary equipment will be provided dependent on local arrangements and regulations.

TRAINING IN ADMINISTRATION OF CEREZYME®

The initial instructions and training will be given by your treating doctor. The level of support

required from the home care nurse will be discussed and agreed upon by you and/or your caregiver and your treating doctor.
Should you prefer support to receive your infusion at home, the home care nurse will carry out the entire procedure for you.
Should you prefer to carry out the procedure yourself or with the assistance of your caregiver, you and/or your caregiver will receive training from the nurse and treating physician while the infusion is being prepared. The home care nurse will explain and demonstrate the complete infusion procedure to you and/or your caregiver.
At subsequent visits, the home care nurse will be present to assist if required, but you and/or your caregiver will gradually transition to performing more of the administration under the home care nurse's supervision until you feel confident with the entire infusion procedure.
While reconstituting and administering CEREZYME®, the procedure described in the Patient information leaflet must be closely followed.

HOW DO I PREPARE AND ADMINISTER CEREZYME®?

Requisites

Supplied by the hospital/pharmacy to you or to a third party with the appropriate prescription.

- Vials of CEREZYME® 400 (400 U per vial); Must be stored at a temperature of between +2°C and +8°C - in a refrigerator.
- Sterile water for injections (10.2 mL per vial) is required to reconstitute CEREZYME®
- NaCl 0.9% solution, 100 - 200 mL for IV administration
- NaCl 0.9% solution, 2 x 50 mL to flush infusion line pre- and post-infusion
- Chlorhexidine 0.5% in Alcohol 70% (antiseptic solution)
- Appropriate number of 10 mL, 20 mL and 50 mL syringes depending upon dose of CEREZYME®
- 3 x sterile hypodermic needles (1.1 x 40 mm)
- 1 x butterfly needle
- In line low protein-binding 0.2 micron filter
- Hypodermic needle tray
- Micropore tape
- Mediswabs
- Sharps bin
- Hand wash
- Additional requisites if using a venous access device
  - Heparin
  - Needles for Heparin
  - Dressing pack
  - Sterile gloves

Preparations

1. Prepare a clean work area and lay out the requisites.
2. The vials with CEREZYME® should be removed from the refrigerator to reach room temperature approximately 30 minutes before preparation
3. Check the expiry date printed on the bottom of the vial pack (do not use CEREZYME® after the expiry date).
4. Verify if the number of vials received is correct.
5. Prepare only the number of vials required for one infusion (Note: CEREZYME® may not be stored in reconstituted or diluted form for later use).

Reconstituting CEREZYME®

1. Remove the flip-off cap from the CEREZYME® vial.
2. Disinfect the rubber stopper of the CEREZYME® vial with chlorhexidine and allow to air dry.
3. Open the sterile water for injections.
4. Draw the required number of mL of sterile water into the syringe. **Reconstitute each vial with 10.2 mL water for injections;** the reconstituted volume is 10.6 mL.
5. Inject the water gently to the inside wall of each vial of CEREZYME® (avoid forceful impact of water for injections on the powder).
6. Repeat the process for more CEREZYME® vials if required.
7. Carefully swirl the vial(s) to mix the solution (avoid forceful shaking during the reconstitution process to avoid foaming of the solution).
8. Small bubbles may appear after the gentle mixing.
9. Let the solution settle for a few minutes to allow any bubbles present to disappear and to ensure that the powder is properly reconstituted.
10. After reconstitution, CEREZYME® should be inspected visually before use. The reconstituted solution must be a clear, colourless liquid, free from foreign matter.
11. If you notice foreign matter or discolouration of the liquid, do not use the product and contact the home care nurse or treating doctor.

Dilution

1. Disinfect the cap/opening of the NaCl 0.9% solution bag using chlorhexidine and allow to air dry.
2. Calculate the quantity of reconstituted CEREZYME® solution present in the vials and draw the same quantity from the bag of NaCl 0.9% solution, thus creating enough space to add the reconstituted CEREZYME® solution.
   For instance, if the prescribed quantity is 7 vials of CEREZYME® of 400 units each, remove 70 mL (=7 x 10 mL) of NaCl solution from the bag of NaCl solution. Never remove more than half the content of the bag of NaCl to ensure that at least half the diluted solution consists of NaCl.
3. Using one or more 20 or 50 mL syringes, **withdraw 10 mL from each of the CEREZYME® vials** and combine the withdrawn volumes. At the point when these quantities are withdrawn, the reconstituted product should not contain any foam.
4. Then gently inject the total volume of the reconstituted CEREZYME® solution into the bag of NaCl 0.9% solution.
5. Gently rotate, invert or massage the infusion bag.
6. Do not shake the solution.
7. The appropriate amount of CEREZYME® for each patient is diluted with 0,9 % sodium chloride injection solution, to a final volume of 100 – 200 mL.
8. Because CEREZYME® is a protein solution, slight flocculation (described as thin translucent fibres) occurs occasionally after dilution. The diluted solution should be filtered through an in-line low protein-binding 0.2 micron filter during administration

Filling the infusion line

1. Remove the infusion system from the package and close it using the roller clamp.
2. Connect the spike in the NaCl 0.9% bag and fill the infusion system by holding the drip chamber upside down and opening the clamp.
3. Fill the entire system, remove any air bubbles that may be present and close the roller clamp.
4. Connect the infusion bag containing CEREZYME® to the y-system.

Inserting the needle in the vein

1. Ensure that some strips of sticking plaster are hanging ready for use and that the start of the infusion system is within reach. Place the chlorhexidine close by, along with some gauzes.
2. Remove the butterfly needle from the packaging.
3. Sit down and rest one arm on the table (preferably on a clean cloth).
4. Apply the tourniquet and disinfect the area where the needle is to be inserted and allow it to dry.
5. Pull the skin tight and insert the needle (with its eye facing upward) at a slight angle through the skin and into the vein. When the needle has entered the vein, a 'flash' of blood will be visible at the start of the tubing.
6. Insert the needle approximately 0.5 cm in the vein to ensure that it does not immediately pop out again. Tape the butterfly needle into place using a plaster.
7. Loosen the tourniquet and remove the cap from the tube. The tube will now fill up with blood. If this does not happen, the needle is not positioned correctly in the vein. The process must then be repeated using a new needle.
8. Attach the prepared infusion bag to the drip stand and open the valve (refer to the infusion rate specified by the treating health care provider in the Logbook). Sit down and relax while the infusion takes place.

Administration

Do not infuse CEREZYME® in the same IV line with other products

The reconstituted and diluted solution is administered by intravenous infusion over 1 - 2 hours, and should be administered within 3 hours of having been prepared.

The product diluted in NaCl 0.9% solution will retain chemical stability if stored up to 24 hours at a temperature between 2°C and 8°C away from light.

The CEREZYME® dose, infusion rate as well as any changes will be determined by the treating doctor.

After the CEREZYME® infusion has been completed, the system is flushed with NaCl 0.9% solution at the same rate and the needle removed.

In case of a central venous access device

When you have a venous access device for the delivery of CEREZYME®, you and/or your caregiver will be shown how to care for the device.

Proper home care of a venous access device involves regular irrigation with a drug called heparin to prevent clotting and attention to a sterile technique to keep the device free of infection. The following steps are necessary:

- When in use, cover site with transparent occlusive dressing.
  No dressing required when not in use.
- Flush with 5 mL saline before and after each use.
- Flush with 5 mL heparin (100 U/mL) after each use.

Safety assessments

Should infusion side effects occur, or if you feel unwell when taking the treatment or after the treatment, contact the home care nurse or the treating doctor immediately. Any side effects should also be recorded in the logbook.

If you become aware that a mistake was made in the preparation and/or administration of the medicine, please contact the home care nurse or the treating doctor immediately.

4. APPENDICES

4.1. Logbook

4.2. Patient Information Leaflet

4.1: LOG BOOK

General Data		
Patient	Name:	
	Address:	
	Postal Code:	
	Telephone:	
Nurse	Name:	
	Organisation:	
	Telephone:	
Treating Health Care provider	Name:	
	Hospital	
	Address:	
	Telephone:	
Pharmacy	Name:	
	Place:	
	Telephone:	
Emergency number	Telephone:	

Administration details and dosing regimen (To be completed by treating health care provider)	
Dose:	
Frequency:	
Rate of infusion:	
Required reconstituted volume (mL)	
Total volume in infusion bag (mL)	
Pre-treatment medication (if applicable):	
Findings and actions from initial interview	
CEREZYME® administered since	Date (dd-mmm-yyyy):
First infusion at home	Date (dd-mmm-yyyy):
Reasons for CEREZYME® infusion at home	
Indicate support to be provided by infusion nurse at home	

Infusion data	
Date of infusion	Date (dd-mmm-yyyy):
Clinical status	
Dose	
Number of vials used	
Duration of administration	
Rate of administration	
Problems/Remarks	

Date of infusion	Date (dd-mmm-yyyy):
Clinical status	
Dose	
Number of vials used	
Duration of administration	
Rate of administration	
Problems/Remarks	

Date of infusion	Date (dd-mmm-yyyy):
Clinical status	
Dose	
Number of vials used	
Duration of administration	
Rate of administration	
Problems/Remarks	

Date of infusion	Date (dd-mmm-yyyy):
Clinical status	
Dose	
Number of vials used	
Duration of administration	
Rate of administration	
Problems/Remarks	

4.2. APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

CEREZYME 400 powder for concentrate for solution for infusion

Imiglucerase

Contains sugar alcohol: each reconstituted vial contains 320 mg mannitol per 10 mL.

Read all of this leaflet carefully before you start receiving CEREZYME.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- CEREZYME has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

1. What CEREZYME is and what it is used for
2. What you need to know before you receive CEREZYME
3. How CEREZYME is administered
4. Possible side effects
5. How to store CEREZYME
6. Contents of the pack and other information.

1. What CEREZYME is and what it is used for

CEREZYME is indicated for long-term enzyme replacement therapy for paediatric and adult patients with a confirmed diagnosis of Type I or Type 3 Gaucher disease that results in one or more of the following conditions:

a. anaemia (low number of red blood cells) after exclusion of other causes such as iron deficiency ,
b. thrombocytopenia (a tendency to bleed easily due to low numbers of platelets – a type of blood cell),
c. bone disease after exclusion of other causes such as vitamin D deficiency , and
d. hepatomegaly or splenomegaly (spleen or liver enlargement).

People with Gaucher disease have low levels of an enzyme called ß-glucocerebrosidase. This enzyme helps the body control levels of glucocerebroside. Glucocerebroside is a natural substance in the body, made of sugar and fat. In Gaucher disease, glucocerebroside levels can get too high.

CEREZYME is an artificial enzyme called imiglucerase. This can replace the natural enzyme acid ß-glucocerebrosidase, which is lacking or not active enough in patients with Gaucher disease.

2. What you need to know before you receive CEREZYME

Do not receive CEREZYME

If you are allergic (hypersensitive) to imiglucerase or any of the other ingredients of CEREZYME (listed in section 6).

Warnings and precautions

Take special care with CEREZYME:

- If you are treated with CEREZYME, you may experience an allergic reaction while you are receiving CEREZYME or shortly thereafter (see section 4 for the symptoms of an allergic reaction). If you experience a reaction like this, you should tell your doctor immediately. Your doctor may perform a test, to determine if you have an allergic reaction to CEREZYME.
- If you experience high blood pressure in the lungs (pulmonary hypertension) while having Gaucher disease. The cause can be unknown, or it can be due to heart, lung or liver problems. It can occur whether the patient is treated with CEREZYME or not. However, if you suffer from any shortness of breath, you should contact your doctor immediately.

Other medicines and CEREZYME

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

CEREZYME with food and drink

CEREZYME may be given with or without food.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before receiving CEREZYME.

It is not known whether CEREZYME is excreted in human milk.

Driving and using machines

Do not drive a vehicle or operate any machinery requiring your attention, until you know how you will react to CEREZYME.

CEREZYME contains sodium chloride

CEREZYME contains approximately 34 mg sodium per reconstituted vial (i.e. 3,4 mg/mL), equivalent to 1,7 % of the WHO recommended maximum daily intake of 2 g sodium for an adult. Additionally, CEREZYME is administered in 0,9 % sodium chloride intravenous solution (see section 6.6). To be taken into consideration by patients on a sodium-controlled diet.

3. How CEREZYME is administered

Do not share medicines prescribed for you with any other person.

Always use CEREZYME exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how long your treatment with CEREZYME will last. If you have the impression that the effect of CEREZYME is too strong or too weak, talk to your doctor or pharmacist.

Each vial of CEREZYME is for single use only.

CEREZYME is administered through a drip into a vein (intravenous infusion) over 1 – 2 hours.

At initial infusions, CEREZYME should be administered at a rate not exceeding 0,5 units/kg/min. At subsequent administrations, infusion rate may be increased, but should not exceed 1 unit/kg/min. Infusion rate increases should occur under the supervision of your doctor.

Your dose will be specific to you. Your doctor will calculate your dose, based on how severe your symptoms are, and other factors. The recommended dose of CEREZYME is 60 units/kilogram body weight, given once every 2 weeks.

Your doctor will closely monitor your response to your treatment, and may adjust your dose (up or down) until he/she finds the best dose to control your symptoms. Once this dose is found, your doctor will still monitor your responses to make sure you are using the right dose. This might be every 6 to 12 months.

Instructions for reconstitution and dilution

CEREZYME powder for concentrate for solution for infusion has to be reconstituted with sterile water for injection, diluted with 0,9 % sodium chloride intravenous solution and then administered by intravenous infusion.

Determine the number of vials to be reconstituted, based on your individual dosage regimen and take the vials from the refrigerator.

Occasionally, small dosage adjustments may be made to avoid discarding partially used vials. Dosages may be rounded to the nearest full vial, as long as the monthly administered dosage remains substantially the same.

Use aseptic techniques.

Reconstitution:

Reconstitute each vial with 10,2 mL sterile water for injection. Avoid forceful impact of water for injections on the powder and, by mixing gently, avoid foaming of the solution. The reconstituted volume is 10,6 mL. The pH of the reconstituted solution is approximately 6,1.

The final concentration and administration volume are provided in the following table:

	400 unit vial
Sterile water for reconstitution	10,2 mL
Final volume of reconstituted product	10,6 mL
Concentration after reconstitution	40 units/mL
Withdrawal volume	10,0 mL
Units of enzyme within final volume	400 units

After reconstitution, the solution is a clear, colourless liquid, free from foreign matter. The reconstituted solution should be further diluted. Before further dilution, visually inspect the reconstituted solution in each vial for foreign particles and discolouration. Do not use vials exhibiting foreign particles or discolouration. Since CEREZYME does not contain any preservatives, vials should be promptly diluted after reconstitution and not be stored for subsequent use.

For in-use storage time after reconstitution, see section 5.

Dilution:
The reconstituted solution contains 40 units imiglucerase per mL. The reconstituted volume allows accurate withdrawal of 10,0 mL (equal to 400 units) from each vial. Withdraw 10,0 mL reconstituted solution from each vial and combine the withdrawn volumes. The appropriate amount of CEREZYME for each patient is diluted with 0,9 % sodium chloride injection, to a final volume of 100 – 200 mL.

Administration:
Because CEREZYME is a protein solution, slight flocculation (described as thin translucent fibres) occurs occasionally after dilution. The diluted solution may be filtered through an in-line low protein-binding 0,2 µm filter during administration in order to remove any protein particles. This will not lead to any loss of imiglucerase activity. It is recommended that the diluted solution be administered within 3 hours. The product diluted in 0,9 % sodium chloride intravenous solution will retain chemical stability if stored up to 24 hours at 2 °C to 8 °C under protection from light; microbiological safety will depend on the reconstitution and dilution having been performed aseptically.

For in-use storage time after dilution, refer to section 5.

Home infusion

If you have tolerated your infusions well for several months, infusion of CEREZYME at home may be considered.

Your doctor may recommend that you can be treated at home, provided you meet certain criteria.
Infusion of CEREZYME by yourself or your caregiver at home, requires training by a health care professional in a clinical setting.
You or your caregiver will be instructed in infusion technique and the keeping of a treatment diary.

If you experience any adverse events during the infusion, you should stop the infusion process and contact your doctor immediately.

Subsequent infusions may need to occur in a clinical setting.

Your dose and infusion rate should remain constant while at home, and not be changed without supervision of your doctor.

If you receive more CEREZYME than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre immediately. Take this leaflet with you so your doctor will know what you have used.

If a dose of CEREZYME was missed

If you have missed an infusion, please contact your doctor.

4. Possible side effects

CEREZYME can have side effects.

Not all side effects reported for CEREZYME are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving CEREZYME, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens, stop using CEREZYME and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to CEREZYME. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following: *Common (occurring in more than 1 in 100 patients)*

- Fever.
- Blue tinge to the nails, lips or face due to insufficient oxygen in the blood.
- Abnormal fast heart rate.
- Chest discomfort.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor as soon as possible if you notice any of the following:
Common (occurring in more than 1 in 100 patients):

- Dizziness, headache.
- Flushing, low blood pressure.
- Coughing.
- Nausea, stomach pain, vomiting, diarrhoea.
- Backache.
- Unusual weakness or tiredness.
- Chills (feelings of coldness, accompanied by shivering).

Uncommon (occurring in more than 1 in 1 000 patients)

- Burning, swelling, sterile abscess at injection site.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to:

- The Pharmacovigilance Unit at Sanofi: za.drugsafety@sanofi.com (email) or 011 256 3700 (tel), or
- SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8

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

5. How to store CEREZYME®

Store at 2 °C to 8 °C (in a refrigerator).
STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
CEREZYME, after reconstitution, has been shown to be stable for up to 12 hours when stored at room temperature (25 °C) and at 2 – 8 °C. CEREZYME, when diluted, has been shown to be stable for up to 24 hours when stored at 2 – 8 °C, protected from light.
Microbiological safety will depend on the reconstitution and dilution having been performed aseptically.
Do not use CEREZYME after the expiration date on the vial.
Discard any unused portion of the solution. Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What CEREZYME contains

CEREZYME contains imiglucerase.
Each reconstituted vial contains 400 units imiglucerase per 10 mL (40 units per 1 mL).
The other ingredients are trisodium citrate, disodium hydrogen citrate, mannitol, and polysorbate 80.

What CEREZYME looks like and contents of the pack

CEREZYME is supplied as a sterile, non-pyrogenic, white to off-white lyophilised cake of powder.
The reconstituted powder is a clear, colourless liquid, free from foreign matter.

The sterile lyophilised powder is packed into 20 mL clear glass vials, each packed into a unit carton.
Pack size: 1 vial.

Holder of certificate of registration:

sanofi-aventis south africa (pty) ltd,
Hertford Office Park, Building I, 5th Floor
90 Bekker Road, Vorna Valley,
Midrand 2196.
South Africa
Tel. no.: 011 256 3700.

This leaflet was last revised

15 August 2022

Registration number

36/31/0179

Date of registration

7 March 2003

For full prescribing information refer to the professional information approved by the medicines regulatory authority.
SOUTH AFRICA: S4 **CEREZYME® 400** (powder for concentrate for solution for infusion).
QUALITATIVE AND QUANTITATIVE COMPOSITION: Each reconstituted vial contains 400 units imiglucerase per 10 mL (40 U/mL).
REGISTRATION NUMBER: 36/31/0179.
NAMIBIA: NS2 **CEREZYME® 400** (powder for concentrate for solution for infusion).
QUALITATIVE AND QUANTITATIVE COMPOSITION: Each reconstituted vial contains 400 units imiglucerase per 10 mL (40 U/mL).
REGISTRATION NUMBER: 14/31/0064.
HOLDER OF CERTIFICATE OF REGISTRATION: sanofi-aventis south africa (pty) ltd., Reg. no.: 1996/010381/07, Floor 5, Building I, Hertford Office Park, 90 Bekker Road, Midrand, 2196. Tel: (011) 256 3700.
MAT-ZA-2300896-1.0-06/2024

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