

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new. Please report side effects. See the [full CMI](#) for further details.

1. Why am I being given Nexviazyme?

Nexviazyme contains the active ingredient avalglucosidase alfa. Nexviazyme is used to treat Pompe disease in patients one year of age and older.

For more information, see Section [1. Why am I being given Nexviazyme?](#) in the full CMI.

2. What should I know before I am given Nexviazyme?

Do not use if you have had an allergic reaction to Nexviazyme or any of the ingredients listed at the end of the CMI, and re-administration of the medicine was not successful.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I am given Nexviazyme?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Nexviazyme and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How will Nexviazyme be given?

- Your doctor or nurse will give you Nexviazyme into a vein (intravenously) as a drip infusion.

More instructions can be found in Section [4. How will Nexviazyme be given?](#) in the full CMI.

5. What should I know while being given Nexviazyme?

| | |
|------------------------------------|--|
| Things you should do | <ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you are using Nexviazyme.It is important to keep your appointments to make sure the medicine works. |
| Things you should not do | <ul style="list-style-type: none">Do not stop your treatment with Nexviazyme unless you have discussed it with your doctor. |
| Driving or using machines | <ul style="list-style-type: none">Take care when driving shortly after infusion of Nexviazyme, since you may experience dizziness |
| Looking after your medicine | <ul style="list-style-type: none">Nexviazyme will be stored at the hospital or clinic in a refrigerator |

For more information, see Section [5. What should I know while being given Nexviazyme?](#) in the full CMI.

6. Are there any side effects?

Infusion reactions have been observed with the use of Nexviazyme.

Common side effects include headache, dizziness, cough, difficulty breathing, nausea, diarrhoea, vomiting, itchy skin, hives, rash, redness of skin, muscle spasms, muscle aches, pain in arm or leg, fatigue, chills, chest discomfort and pain.

Serious side effects may include allergic reactions with symptoms such as difficulty breathing, chest discomfort, flushing, dizziness, nausea, redness on palms and feet, itchy palms and feet, swollen lower lip and tongue, and rash.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

▼ 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. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

Nexviazyme®

Active ingredient(s): *avalglucosidase alfa*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Nexviazyme. **You should also speak to your doctor, nurse, or pharmacist if you would like further information or if you have any concerns or questions about using Nexviazyme.**

Where to find information in this leaflet:

1. [Why am I being given Nexviazyme?](#)
2. [What should I know before I am given Nexviazyme?](#)
3. [What if I am taking other medicines?](#)
4. [How will Nexviazyme be given?](#)
5. [What should I know while being given Nexviazyme?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I being given Nexviazyme?

Nexviazyme contains the active ingredient avalglucosidase alfa. Avalglucosidase alfa is an artificial enzyme that can replace the natural enzyme that is lacking in Pompe disease.

Nexviazyme is used to treat Pompe disease. Pompe disease is a rare genetic disease in which the level of an enzyme called acid alfa-glucosidase is missing or is lower than in healthy individuals. This enzyme helps the body control levels of glycogen (a type of carbohydrate).

2. What should I know before I am given Nexviazyme?

Warnings

Do not use Nexviazyme if:

- you have a severe life-threatening allergic reaction to avalglucosidase alfa, or any of the ingredients listed at the end of this leaflet, and these reactions occurred again after stopping and restarting the medicine
- always check the ingredients to make sure you can use this medicine.

Tell your doctor if you:

- have any other medical conditions
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. There is no experience with the use of Nexviazyme in pregnant women.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Use in children

- Nexviazyme has been studied in patients older than one year of age

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop

Some medicines may interfere with Nexviazyme and affect how it works.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Nexviazyme.

4. How will Nexviazyme be given?

How much to use

- You will be given Nexviazyme under the supervision of your doctor or a nurse.
- The dose you receive is based on your body weight.
- The recommended dose is 20 mg/kg of body weight.

When to use Nexviazyme

- Nexviazyme will be given to you every other week.

How to inject Nexviazyme

- Nexviazyme is given through a drip into a vein (intravenous infusion), usually in the arm.
- Infusion takes approximately 4 hours for people with late-onset Pompe disease and approximately 6 hours for children with infantile-onset Pompe disease.
- If you are tolerating your infusions well, your doctor may consider home infusion. This decision should be made after careful consideration of the risks and benefits by the doctor. If you experience a side effect during infusion, the doctor or nurse may stop the infusion and initiate appropriate medical treatment.

Medicines given before infusion of Nexviazyme

You may be given medicines to prevent or reduce an allergic reaction such as antihistamines and or corticosteroids, or to reduce fever.

If you forget to use Nexviazyme

It is very important that you go to all your appointments to make sure your treatment works. If you miss any appointments, call your doctor or nurse as soon as possible to reschedule your appointment. Your doctor or nurse will decide how your treatment should be continued.

If you are given too much Nexviazyme

Faster infusion of Nexviazyme may result in occurrence of infusion related side effects. If you experience a reaction similar to this, tell your doctor or nurse immediately. Your doctor or nurse is trained to calculate the correct dose. If you are given too much (an overdose) your doctor or nurse will treat and monitor your side effects.

5. What should I know while being given Nexviazyme?

Things you should do

Keep your appointments.

It is important to have your infusion with Nexviazyme at the appropriate times to make sure the medicine has the best chance of providing treatment for the condition.

Have any tests when your doctor says to.

Your doctor may recommend to perform blood tests to monitor your body's response to Nexviazyme to make sure that it is working.

Remind any doctor, dentist or pharmacist you visit that you are using Nexviazyme.

Infusion-related reactions

Infusion reactions can happen during Nexviazyme infusion or after the infusion. Tell your doctor or nurse straight away if you experience symptoms listed in the Side Effects section during or after the infusion of Nexviazyme.

Your condition will be monitored closely during treatment.

In case of infusion reactions, your doctor or nurse may decide to give you additional medicines to treat your symptoms and prevent complications, or temporarily stop the infusion, slow it down, or completely stop it.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Nexviazyme affects you. Take care when driving shortly after infusion of Nexviazyme, since you may experience dizziness, low blood pressure, and tiredness.

Looking after your medicine

- Nexviazyme can be stored up to 24 hours when refrigerated at 2°C to 8°C and diluted product can be stored up to 24 hours when refrigerated at 2°C to 8°C

and up to 9 hours (including infusion time) when stored at room temperature.

Keep it where young children cannot reach it.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

| Less serious side effects | What to do |
|--|---|
| Mild to moderate infusion-related side effects: Respiratory-related <ul style="list-style-type: none">CoughFlu like symptoms Skin-related <ul style="list-style-type: none">Redness of skinItchy skinHivesRash Stomach-related <ul style="list-style-type: none">VomitingDiarrhoea Muscle and joint-related <ul style="list-style-type: none">Muscle spasmsMuscle achesPain in arm or leg Other <ul style="list-style-type: none">FatiguePainChillsInjection site painSwollen eyelid and/or faceFeeling cold | Speak to your doctor or nurse if you have any of these less serious side effects and they worry you. |

Serious side effects

| Serious side effects | What to do |
|---|--|
| Infusion related side effects: Heart-related <ul style="list-style-type: none">Fast heart beatChest discomfort | Call your doctor straight away, or go straight to the Emergency Department at |

| Serious side effects | What to do |
|--|--|
| <ul style="list-style-type: none"> Increased or decreased blood pressure <p>Respiratory-related</p> <ul style="list-style-type: none"> Difficulty breathing or swallowing Low blood oxygen <p>Skin-related</p> <ul style="list-style-type: none"> Rash Redness on palms and feet Skin discolouration Itchy palms and feet <p>Other</p> <ul style="list-style-type: none"> Headache Fever Flushing Dizziness Tremor (shaking) Nausea Swollen lower lip and tongue | <p>your nearest hospital if you notice any of these serious side effects.</p> |

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Nexviazyme contains

| | |
|---|--|
| Active ingredient (main ingredient) | Avalglucosidase alfa |
| Other ingredients (inactive ingredients) | Histidine Histidine hydrochloride monohydrate Glycine Mannitol Polysorbate |

Do not take this medicine if you are allergic to any of these ingredients.

What Nexviazyme looks like

Nexviazyme is a white to pale yellow powder in a vial which is reconstituted and diluted before infusion.

The strength is 100mg/10mL.

Each pack contains 1 vial.

Aust R 346495

Who distributes Nexviazyme

Distributed by:

sanofi-aventis australia pty ltd

International Tower 3, Level 23

300 Barangaroo Avenue

Sydney NSW 2000

Freecall: 1800 818 806

Email: medinfo.australia@sanofi.com

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