Nexviazyme®

Active ingredient(s): avalglucosidase alfa

Consumer Medicine Information

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 alfaglucosidase 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 lifethreatening 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.