PATIENT INFORMATION
INFILBRAY (IN fill bray)
(venglustat)
tablets, for oral use

What is INFILBRAY?

INFILBRAY is a prescription medicine used for the treatment of neurological (nervous system) symptoms in Type 3 Gaucher disease (GD3) in adults and children weighing at least 33 pounds (15 kg).
It is not known if INFILBRAY is safe and effective in children under 33 pounds (15 kg).

Before taking INFILBRAY, tell your healthcare provider about all of your medical conditions, including if you:

- have kidney problems.
- have or have had a history of suicidal thoughts and actions, depression, or any other mental health problem.
- are pregnant or plan to become pregnant. INFILBRAY may harm your unborn baby.
  Females who are able to become pregnant:
  - Your healthcare provider will do a pregnancy test before you start treatment with INFILBRAY.
  - Use effective birth control (contraception) during treatment and for 11 days after the last dose of INFILBRAY.
  - Tell your healthcare provider right away if you become pregnant or think that you may be pregnant during treatment with INFILBRAY.
- are breastfeeding or plan to breastfeed. It is not known if INFILBRAY passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you take INFILBRAY. If you breastfeed during treatment with INFILBRAY, your baby may need eye exams with an eye specialist (ophthalmologist).

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking INFILBRAY with certain other medicines may affect how INFILBRAY works and increase the risk of side effects.

How should I take INFILBRAY?

- Take INFILBRAY exactly as your healthcare provider tells you to take it.
- Your healthcare provider may change your dose or when you take INFILBRAY if you take certain medicines.
- Your child's healthcare provider will prescribe INFILBRAY based on your child's weight.
- Take INFILBRAY 1 time a day.
- Take INFILBRAY with or without food.
- Swallow INFILBRAY tablet(s) whole or chew the tablet(s) first and then swallow.
- If you cannot swallow INFILBRAY tablets whole or chew the tablet(s), INFILBRAY can be crushed and mixed with liquids or soft foods if taken within 30 minutes after mixing.
- If you miss a dose of INFILBRAY by more than 12 hours, skip the missed dose and take the next dose at the regularly scheduled time. Do not take two doses of INFILBRAY at the same time.
- If you vomit after taking INFILBRAY, do not take another dose. Take the next dose at the regularly scheduled time. Do not take two doses of INFILBRAY at the same time.

What should I avoid while taking INFILBRAY?

- You should not drink grapefruit juice, eat grapefruit, or eat Seville oranges (often in marmalades) while you are taking INFILBRAY. These products may increase the amount of INFILBRAY in your blood**.**

What are the possible side effects of INFILBRAY?

INFILBRAY may cause serious side effects, including:

- **Suicidal thoughts or actions.** INFILBRAY may cause suicidal thoughts or actions, depression, or other mood changes. Before starting treatment with INFILBRAY, your healthcare provider will check your risk for mental health problems. Pay close attention to, and tell your healthcare provider about any behavior changes, especially suicidal thoughts or actions, new or worsening changes in depression, mood, behaviors, thoughts, or feelings.

  Tell a healthcare provider right away if you have any of the following symptoms, especially if they are new, worse, or worry you:

  - thoughts about suicide or dying
  - suicide attempts
  - new or worsening depression
  - new or worsening anxiety
  - feeling very agitated or restless
  - panic attacks
  - trouble sleeping (insomnia)
  - new or worsening irritability
  - acting aggressive, being angry, or violent
  - acting on dangerous impulses
  - an extreme increase in activity and talking (mania)
  - other unusual changes in behavior or mood

  Your healthcare provider may stop treatment with INFILBRAY if you develop mental health problems.

- **Clouding of the eye's lens (lens opacification) in children.** Cloudiness of the eye lens may happen in children during long-term (chronic) treatment with INFILBRAY. Children will have their eyes checked by an eye specialist (ophthalmologist) before and once a year during treatment with INFILBRAY. Tell your healthcare provider if your child gets any vision changes during treatment with INFILBRAY including clouded, blurred, or dim vision, trouble seeing in sunlight or bright lights, and trouble seeing at night.

The most common side effects of INFILBRAY include:

- diarrhea
- nausea
- irritation or infection of the stomach and intestine (gastroenteritis)
- enlarged spleen
- depression
- vomiting

These are not all of the possible side effects of INFILBRAY.
Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store INFILBRAY?

- Store INFILBRAY at room temperature, between 68°F to 77°F (20°C to 25°C).
- Store INFILBRAY in the original package to protect from moisture.
- Do not remove INFILBRAY tablets from the blister card until right before taking.
- INFILBRAY tablets are packaged in blister cards in a child-resistant carton.

Keep INFILBRAY and all medicines out of the reach of children.

General information about the safe and effective use of INFILBRAY.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use INFILBRAY for a condition for which it was not prescribed. Do not give INFILBRAY to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about INFILBRAY that is written for health professionals.

What are the ingredients in INFILBRAY?

Active ingredients: venglustat
Inactive ingredients: apricot flavor (acetic acid, maltodextrin, natural flavoring substances, starch modified corn, triacetin), colloidal silicon dioxide, crospovidone, low substituted hydroxypropylcellulose, magnesium stearate, mannitol, and sodium stearyl fumarate

Manufactured by: Genzyme Corporation, 450 Water Street, Cambridge, MA 02141 A SANOFI COMPANY
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For more information, go to https://www.infilbray.com/us or call 1-800-633-1610.

This Patient Information has been approved by the U.S. Food and Drug Administration. Issued: 11/2026