Infilbray™ venglustat 6 mg | 15 mg tablets

# Helping Patients Start on Treatment With Infilbray

**On November 18, 2026, Infilbray received FDA approval as the first and only therapy to treat the neurological manifestations of Type 3 Gaucher disease (GD3) in patients weighing at least 15 kg—a breakthrough in neurologic care![1]**

## Enrolling in CareConnect™ can help patients start and stay on treatment with Infilbray

### If your patient is already enrolled

- Connect with your patient's dedicated Case Manager for assistance during the treatment initiation process

### If your patient is NOT enrolled

- Inform patients to fill out the online enrollment form or contact a Case Manager by calling 1-800-745-444 , option 3, or emailing info@CareConnectPSS.com

Infilbray can be purchased through authorized distributors, most specialty pharmacies, or directly through Sanofi. For more information, connect with your patient's dedicated Case Manager upon enrollment in CareConnect; contact Sanofi's Rare Disease Product Services team at 1-800-745-4447, option 1; or email CO@Sanofi.com.



**The prior authorization (PA) checklist is available as an informational resource for the PA process, as are additional resources to help patients start treatment with Infilbray. These resources can be found at HCP resources**

FDA, US Food and Drug Administration.

## Indication

INFILBRAY (venglustat) is indicated for the treatment of neurological manifestations of Type 3 Gaucher disease (GD3) in patients weighing at least 15 kg.

## Important Safety Information

### Warnings and Precautions:

#### Suicidal Ideation and Behavior:

Suicidal ideation and behavior have been reported in patients with GD3 receiving INFILBRAY and in unapproved populations receiving another formulation of venglustat, both with and without a history of psychiatric disorders. Assess patients' underlying risk of psychiatric disorders prior to initiation and monitor for depressive symptoms or suicidal thoughts during treatment.

**Please see Important Safety Information throughout and Full Prescribing Information for INFILBRAY.**

# Key product information

## NDC/ICD coding[1]

| NDC | Strength | Package Configuration |
|---|---|---|
| NDC 10 58468-2006-1 | 6 mg | Carton containing 28 tablets (1 blister card of 28 tablets) |
| NDC 11 58468-2006-01 | | |
| NDC 10 58468-2015-1 | 15 mg | Carton containing 28 tablets (1 blister card of 28 tablets) |
| NDC 11 58468-2015-01 | | |

***ICD-10-CM* code**: E75.22, Description: Gaucher disease.[2,a]

## Dosage and administration[1]

Infilbray treatment should be initiated and supervised by a healthcare provider experienced in the management of GD3. Prior to treatment initiation

- Assess patients' underlying risk of psychiatric disorders
- Perform an ophthalmologic examination in pediatric patients
- Verify pregnancy status in females of reproductive potential

The recommended dosage in adult patients is 15 mg orally once daily. For pediatric patients weighing ≥15 kg, dosing should be adjusted based on body weight.

| Age Group | Body Weight | Recommended Dosage |
|---|---|---|
| 6 years of age to less than 18 years of age | 50 kg and above | 15 mg orally once daily |
| | 15 to less than 50 kg | 12 mg orally once daily |
| Less than 6 years of age | 30 to less than 50 kg | 12 mg orally once daily |
| | 15 to less than 30 kg | 6 mg orally once daily |

For complete details regarding dosing and drug interactions, please refer to the Infilbray **Full Prescribing Information**.

## How supplied[1]

Infilbray is packaged as 6-mg and 15-mg tablets in blister cards and supplied in child-resistant cartons. Each blister carton contains 28 tablets in a blister card of 28 tablets.

Infilbray 6-mg tablets are white to off-white, oblong, apricot-flavored, and debossed with "6" on one side. Infilbray 15-mg tablets are white to off-white, round, apricot-flavored, and debossed with "15" on one side.

## Storage and handling[1]

Store from 20 °C to 25 °C (68 °F to 77 °F) with excursions permitted between 15 °C and 30 °C (59 °F and 86 °F). Store in the original package in order to protect from moisture. Keep in original package until immediately before administration.

Questions about storage and handling can be addressed by contacting your Sanofi Account Director or the Sanofi Product Information department at **1-800-745-4447, option 2**.

[a]The *ICD-10-CM* code is not all-inclusive. Appropriate codes vary by patient, insurance plan, and care setting. Correct coding is the responsibility of the healthcare professional submitting the claim. Sanofi does not guarantee coverage or reimbursement.

*ICD-10-CM*, International Classification of Diseases, Tenth Edition, Clinical Modification; NDC, National Drug Code.

## Important Safety Information (cont'd)

**Warnings and Precautions:** (cont'd)

**Suicidal Ideation and Behavior:** (cont'd)

Use caution when prescribing to patients with a history of psychiatric disorders. Inform patients or caregivers of the potential for behavioral and mood changes and to seek medical attention for manifestations of suicidal ideation and behavior, new onset or worsening depression, or other mood changes. Consider changing the therapeutic regimen, including possibly discontinuing INFILBRAY, if such events occur.

**Please see Important Safety Information throughout and Full Prescribing Information for INFILBRAY.**

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# Connected care throughout the journey

CareConnect is a free, voluntary, and confidential support program for eligible patients and families living with GD3.

### Connected Education

Comprehensive disease education from diagnosis and beyond for individuals, families, and communities.

### Connected Team

Dedicated team who connects the dots between specialists, insurance, and appointments for a less fragmented care experience.

### Connected Experience

Programs designed to support your patients by connecting them with experts and the community to navigate life transitions and disease management.

# Financial assistance

If affordability is an obstacle in accessing treatment, CareConnect may be able to help by exploring financial assistance programs for eligible individuals.

### Copay Program[a]

Helps eligible patients in the US who are prescribed certain Sanofi therapies pay for eligible out-of-pocket drug costs and specified infusion-related charges, including copays, coinsurance, and deductibles, up to the program maximum.

### Patient Assistance Program

Established in the US to provide certain Sanofi therapies at no cost to eligible patients who do not have health insurance or cannot access an eligible product under the terms of their insurance plan. The program is considered a temporary solution until coverage can be secured.

### Additional Assistance Programs

Designed to solve obstacles eligible patients may encounter while accessing and maintaining therapy.

**Patients must be enrolled in CareConnect to participate in these programs.**

**Connect with your patient's dedicated Case Manager to access the appropriate program(s).**
If you don't have your patient's dedicated contact, call 1-800-745-4447, option 3, or email info@CareConnectPSS.com to reach a Case Manager.

For all programs, patients must reside in the US or a US territory where Infilbray is available. Patients must be treated by a healthcare professional residing in the US. Other eligibility restrictions apply.

[a]Not valid for prescriptions paid, in whole or in part, by Medicaid, Medicare, VA, DOD, TRICARE, or other federal or state programs including any state pharmaceutical assistance programs. No claim for reimbursement of any out-of-pocket costs may be submitted to any third-party payer, whether public or private, including but not limited to patients' insurance, Flexible Spending Account (FSA), Health Savings Account (HSA), or any other type of medical savings account. This program is not valid where prohibited by law, taxed, or restricted. Sanofi reserves the right to rescind, revoke, terminate, or amend this offer, eligibility, and terms of use at any time without notice. Any savings provided on the program may vary depending on patients' out-of-pocket costs. Patients will receive all program details upon registration.

## Important Safety Information (cont'd)

**Warnings and Precautions:** (cont'd)

**Lens Opacification in Pediatric Patients:**

Lens opacification may occur in pediatric patients treated with INFILBRAY. In pediatric patients, perform ophthalmological assessment prior to initiation and annually during treatment. Advise pediatric patients and caregivers to report any visual disturbances during treatment.

**Please see Important Safety Information throughout and Full Prescribing Information for INFILBRAY.**

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## Important Safety Information (cont'd)

### Warnings and Precautions: (cont'd)

**Embryofetal Toxicity:**

Based on animal studies, INFILBRAY may cause fetal harm when administered to a pregnant woman. Prior to initiation, verify pregnancy status in females of reproductive potential and advise them of the potential risk to the fetus. Advise females of reproductive potential to use effective contraception during treatment and for 11 days after the last dose.

**Adverse Reactions:**

The most common adverse reactions reported in ≥10% of INFILBRAY-treated GD3 patients aged ≥12 years were diarrhea, splenomegaly, nausea, depression, gastroenteritis, and vomiting.

**Drug Interactions:**

**Strong CYP3A Inhibitors:** Avoid concomitant use with INFILBRAY. Strong CYP3A inhibitors increase venglustat exposure, which may increase the risk of adverse reactions. If concomitant use is unavoidable, reduce INFILBRAY dosage.

**Strong or Moderate CYP3A Inducers:** Avoid concomitant use with INFILBRAY. Strong or moderate CYP3A inducers decrease venglustat exposure, which may result in decreased efficacy. If concomitant use is unavoidable, monitor for reduced effectiveness.

**Please see Full Prescribing Information for INFILBRAY.**

**References: 1.** Infilbray (venglustat). Prescribing information. Genzyme Corporation, Cambridge, MA. **2.** Centers for Medicare and Medicaid Services. ICD-10-CM tabular list of diseases and injuries. Accessed October 30, 2026. https://ftp.cdc.gov/pub/Health_Statistics/NCHS/Publications/ICD10CM/2027/icd10cm-tabular-2027.pdf

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