HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use INFILBRAY™ safely and effectively. See full prescribing information for INFILBRAY.

INFILBRAY (venglustat) tablets, for oral use
Initial U.S. Approval: 2026

----------INDICATIONS AND USAGE----------

INFILBRAY is a glucosylceramide synthase inhibitor indicated for the treatment of neurological manifestations of Type 3 Gaucher disease (GD3) in adults and pediatric patients weighing at least 15 kg. (1)

----------DOSAGE AND ADMINISTRATION----------

- Therapy with INFILBRAY should be initiated and supervised by a healthcare provider experienced in the management of GD3. (2.1)
- Prior to initiating INFILBRAY: (2.1)
  - Assess patients' underlying risk of psychiatric disorders. (5.1)
  - Perform ophthalmologic examination in pediatric patients. (5.2)
  - Verify pregnancy status in females of reproductive potential. (5.3)
- The recommended dosage in adults is 15 mg orally once daily. (2.2)
- The recommended dosage in pediatric patients weighing at least 15 kg is: (2.3)

Age Group	Body Weight	Recommended Dosage
6 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

- The recommended dosage in adults with an eGFR <30 mL/min is 12 mg orally once daily. (2.4)
- See full prescribing information for INFILBRAY dosage modifications due to drug interactions. (2.5)
- See full prescribing information for administration instructions. (2.6)

----------DOSAGE FORMS AND STRENGTHS----------

Tablets: 6 mg and 15 mg of venglustat (3)

----------CONTRAINDICATIONS----------

None. (4)

----------WARNINGS AND PRECAUTIONS----------

- *Suicidal Ideation and Behavior:* Suicidal ideation and behavior have been reported. Use caution when prescribing INFILBRAY to patients with a history of psychiatric disorders. Monitor for depressive symptoms or suicidal thoughts during treatment. (5.1)
- *Lens Opacification in Pediatric Patients:* Lens opacification may occur in pediatric patients. Perform ophthalmological assessments annually during treatment. Advise pediatric patients and caregivers to report any visual disturbances during treatment. (5.2)
- *Embryofetal Toxicity:* Based on animal studies, may cause fetal harm. Advise female patients of reproductive potential of the potential risk to a fetus and to use effective contraception. (5.3, 8.1, 8.3)

----------ADVERSE REACTIONS----------

The most common adverse reactions (incidence ≥10%) are; diarrhea, splenomegaly, nausea, depression, gastroenteritis, and vomiting. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Genzyme Corporation at 1-800-633-1610 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

----------DRUG INTERACTIONS----------

- *Strong CYP3A Inhibitors:* Avoid concomitant use with INFILBRAY. If concomitant use is unavoidable, reduce INFILBRAY dosage as follows: (7)
  - Adults: 12 mg orally once daily
  - Pediatric patients weighing at least 15 kg:

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

- *Strong or Moderate CYP3A Inducers:* Avoid concomitant use with INFILBRAY. (7)

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 11/2026

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

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

2 DOSAGE AND ADMINISTRATION

2.1 Important Recommendations for Prior to and During INFILBRAY Treatment

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 *[see Warnings and Precautions (5.1)]*.
- Perform an ophthalmologic examination in pediatric patients *[see Warnings and Precautions (5.2)]*.
- Verify pregnancy status in females of reproductive potential *[see Warnings and Precautions (5.3)]*.

2.2 Recommended Dosage in Adults

The recommended dosage of INFILBRAY in adults is 15 mg orally once daily.

2.3 Recommended Dosage in Pediatric Patients

The recommended dosage of INFILBRAY in pediatric patients weighing at least 15 kg is presented in Table 1.

Table 1: Recommended INFILBRAY Dosage in Pediatric Patients Weighing at Least 15 kg

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

2.4 Recommended Dosage in Patients with Renal Impairment

The recommended dosage of INFILBRAY in adults with renal impairment is described in Table 2 *[see Use in Specific Populations (8.6) and Clinical Pharmacology (12.3)]*.

Table 2: Recommended INFILBRAY Dosage in Adults with Renal Impairment

eGFR	Recommended Dosage
≥ 30 mL/min*	Same as adults without renal impairment *[see Dosage and Administration (2.2)]*
< 30 mL/min*	12 mg orally once daily

*If the eGFR for an adult patient is calculated using an equation standardized to a body surface area value of 1.73 m^2 (reported in units of mL/minute/1.73 m^2), then multiply the body surface area-standardized eGFR value by the patient's body surface area and divide by 1.73 to obtain the eGFR in units of mL/minute. Use the eGFR in units of mL/minute to determine the recommended dosage.

The recommended dosage of INFILBRAY in pediatric patients weighing at least 15 kg with renal impairment is described in Table 3 *[see Use in Specific Populations (8.6) and Clinical Pharmacology (12.3)]*.

Table 3: Recommended INFILBRAY Dosage in Pediatric Patients Weighing at Least 15 kg with Renal Impairment

eGFR	Recommended Dosage
≥ 30 mL/min/1.73m²	Same as pediatric patients without renal impairment *[see Dosage and Administration (2.3)]*
< 30 mL/min/1.73m²	No data available to establish a dosage recommendation

2.5 Dosage Modifications for Strong CYP3A Inhibitors

Avoid concomitant use of INFILBRAY with strong CYP3A inhibitors. If concomitant use is unavoidable:

- For adults, reduce the INFILBRAY dosage to 12 mg orally once daily.
- For pediatric patients weighing at least 15 kg, the recommended INFILBRAY dosage is presented in Table 4 *[see Drug Interactions (7)]*.

Table 4: Recommended INFILBRAY Dosage in Pediatric Patients Weighing at Least 15 kg and Receiving a Strong CYP3A Inhibitor

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

2.6 Administration Instructions

Take INFILBRAY orally with or without food. Swallow tablet(s) whole or chew the tablet(s) first and then swallow.

Alternatively, crush and mix INFILBRAY tablets with liquids or soft foods. Administer within 30 minutes after mixing. Do not mix with juice containing grapefruit or Seville oranges *[see Drug Interactions (7)]*.

2.7 Missed Dose or Vomited Dose

If a dose is missed by more than 12 hours, skip the missed dose and take the next dose at the regularly scheduled time.

If vomiting occurs after taking a dose of INFILBRAY, do not take an additional dose. Take the next dose at the regularly scheduled time.

If a dose is missed or vomited, do not double the next scheduled dose.

3 DOSAGE FORMS AND STRENGTHS

Tablets:

- 6 mg of venglustat, white to off-white, oblong, apricot-flavored, debossed with "6" on one side
- 15 mg of venglustat, white to off-white, round, apricot-flavored, debossed with "15" on one side

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Suicidal Ideation and Behavior

Suicidal ideation and behavior have been reported in patients with Type 3 Gaucher disease (GD3) receiving INFILBRAY and in unapproved populations receiving another oral formulation of venglustat, both with and without a history of psychiatric disorders *[see Adverse Reactions (6.1)]*.

Assess patients' underlying risk of psychiatric disorders prior to treatment initiation and monitor for depressive symptoms or suicidal thoughts during treatment with INFILBRAY. Use caution when prescribing INFILBRAY to patients with a history of psychiatric disorders. Inform patients or caregivers of the potential for behavioral and mood changes and encourage them 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.

5.2 Lens Opacification in Pediatric Patients

Lens opacification may occur in pediatric patients treated with INFILBRAY. Preclinical studies in juvenile rats have shown lens degeneration at clinically relevant exposure levels of venglustat *[see Use in Specific Populations (8.4)]*.

Histopathological findings in rats suggest similarities to human cortical cataracts. The clinical relevance of these findings in pediatric patients remains uncertain due to limited information available in clinical trials for the pediatric population.

In pediatric patients, perform ophthalmological assessment prior to INFILBRAY initiation and annually during treatment. Advise pediatric patients and their caregivers to report any visual disturbances during treatment.

5.3 Embryofetal Toxicity

Based on findings from animal studies, INFILBRAY may cause fetal harm when administered to a pregnant woman. Administration of venglustat to pregnant rats at exposures 1.5-fold the exposure at the maximum recommended human dose (MRHD) resulted in increased fetal losses and increased incidence of major visceral abnormalities and minor abnormalities and variations (skeletal). The exposure at the no observed adverse event level (NOAEL) for embryofetal toxicity in rats was approximately 0.2-fold the expected exposure at the MRHD.

Verify pregnancy status of females of reproductive potential prior to starting treatment. Advise pregnant women and females of reproductive potential of the potential risk to the fetus. Advise females of reproductive potential to use effective contraception during treatment with INFILBRAY and for 11 days after the last dose *[see Use in Specific Populations (8.1, 8.3)]*.

6 ADVERSE REACTIONS

The following clinically significant adverse reactions are described elsewhere in the labeling:

- Suicidal Ideation and Behavior *[see Warnings and Precautions (5.1)]*

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The safety of INFILBRAY was evaluated in patients with Type 3 Gaucher disease (GD3) in Study 1, a randomized, double-blind, double-dummy, active-controlled study that included a 52-week double-blind primary analysis treatment period, followed by an open-label treatment period. Out of a total of 43 patients enrolled, 21 patients, including 9 pediatric patients aged 12 to less than 18 years and 12 adults aged 18 years and older, received oral INFILBRAY once daily for 52 weeks during the primary analysis period. Adult patients received INFILBRAY 15 mg. Pediatric patients weighing 50 kg or more received INFILBRAY 15 mg, and those weighing 30 kg to less than 50 kg received INFILBRAY 12 mg *[see Clinical Studies (14)]*.

Adverse reactions that occurred in at least 10% of INFILBRAY-treated patients during the primary analysis period are described in Table 5. The adverse reaction profile observed in pediatric patients aged 12 to less than 18 years did not appear to be different from that observed in adults.

Table 5: Adverse Reactions* in INFILBRAY-Treated Adults and Pediatric Patients Aged 12 to Less Than 18 Years with GD3 During the 52-Week Primary Analysis Period of Study 1

Adverse Reactions	INFILBRAY N = 21 n (%)	Imiglucerase N = 22 n (%)
Diarrhea	3 (14)	0
Splenomegaly	3 (14)	0
Nausea	3 (14)	1 (5)
Depression	2 (10)	0
Gastroenteritis	2 (10)	0
Vomiting	2 (10)	1 (5)

*Adverse reactions occurring at an incidence of ≥10% in INFILBRAY-treated patients and greater than in Imiglucerase-treated patients

In a placebo-controlled pooled analysis of safety data from 362 adult patients exposed to another formulation of venglustat in unapproved populations, depression occurred in 7.7% patients (n = 28) who received venglustat 15 mg orally once daily for a median duration of 52 weeks compared to 5.7% patients (n = 19) who received placebo (n = 340). Suicidal ideation and behavior events occurred in 1% (n = 4) of venglustat treated patients compared to none in placebo patients.

7 DRUG INTERACTIONS

Effects of Other Drugs on INFILBRAY

Strong CYP3A Inhibitors

Avoid concomitant use of INFILBRAY with strong CYP3A inhibitors. If concomitant use is unavoidable, reduce the dosage of INFILBRAY *[see Dosage and Administration (2.5)]*. Avoid consumption of grapefruit or Seville oranges during treatment with INFILBRAY *[see Dosage and Administration (2.6)]*.

Venglustat is a CYP3A substrate. Strong CYP3A inhibitors, including grapefruit or Seville oranges, increase venglustat exposure *[see Clinical Pharmacology (12.3)]*, which may increase the risk of INFILBRAY associated adverse reactions.

Strong or Moderate CYP3A Inducers

Avoid concomitant use of INFILBRAY with strong or moderate CYP3A inducers. If concomitant use is unavoidable, monitor for reduced effectiveness of INFILBRAY.

Venglustat is a CYP3A substrate. Strong or moderate CYP3A inducers decrease venglustat exposure *[see Clinical Pharmacology (12.3)]*, which may result in decreased efficacy of INFILBRAY.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Based on findings in animal studies, INFILBRAY may cause fetal harm when administered to a pregnant woman. Available data with use of INFILBRAY in pregnant women are insufficient to establish a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes.

In animal reproduction studies, early embryo-fetal deaths, post-implantation losses, decreased numbers of live fetuses, and an increased incidence of major visceral abnormalities and minor abnormalities and variations (skeletal) were observed when venglustat was administered orally to pregnant rats during the period of organogenesis at exposures 1.5-fold the expected exposure at the maximum recommended human dose (MRHD). In a study where venglustat was administered to pregnant rabbits during the period of organogenesis, lower fetal weights, reduced gravid uterus and litter weights, and increased incidences of minor variations were observed in the presence of maternal toxicity at exposures 11-fold the expected exposure at the MRHD.

In a pre- and postnatal development study in pregnant rats, increases in duration of gestation as well as fetal resorptions, lower numbers of pups born, lower postnatal survival, and lower pup body weights were observed at exposures 1.5 times the expected exposure at the MRHD *(see Data)*.

The background risk of major birth defects and miscarriage in the indicated population is unknown. All pregnancies have a background risk of birth defects, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Clinical Considerations

Disease-Associated Maternal and/or Embryo/Fetal Risk

Pregnancy may exacerbate existing Type 3 Gaucher disease (GD3) symptoms or result in new disease manifestations. Untreated symptomatic GD3 may lead to complications during pregnancy, including hepatosplenomegaly, which can interfere with the normal growth of a pregnancy, and thrombocytopenia, which can lead to excessive bleeding.

Data

Animal Data

In an embryo-fetal development study, venglustat was administered via oral gavage to pregnant rats during organogenesis (gestational day (GD) 6 to 17) at 0, 2, 5, and 10 mg/kg/day. Decreased fetal and litter weights were observed at maternal doses ≥5 mg/kg/day (0.7 to 1.5-fold the MRHD based on the area under the concentration-time curve (AUC)), and increased early embryo-fetal deaths along with decreases in number of live fetuses were observed at 10 mg/kg/day (1.5-fold the MRHD based on AUC). Increased incidence of major fetal abnormalities in the absence of overt maternal toxicity was observed following dosing at 10 mg/kg with minor variations indicative of developmental delay observed starting at 5 mg/kg/day. A no observed adverse effect level (NOAEL) in rats was determined to be 2 mg/kg/day, approximately 0.2-fold the exposure at the MRHD based on AUC.

In an embryo-fetal development study, venglustat was administered via oral gavage to pregnant rabbits during organogenesis (GD 6 to 18) at 0, 5, 15, and 45 mg/kg/day. Maternal toxicity was observed as decreased body weight gains during gestation and reduced gravid uterus weights at 45 mg/kg/day (11-fold the exposure at the MRHD based on AUC). Fetal toxicity was associated with maternal toxicity and observed as decreased fetal weight and increased incidence of minor variations indicative of delayed ossification at 45 mg/kg/day. A NOAEL in rabbits was determined to be 15 mg/kg/day, corresponding to exposures approximately 3-fold the exposure at the MRHD based on AUC.

In a pre- and postnatal developmental toxicity study, the oral administration of venglustat to pregnant rats at doses of 0, 2, 5 or 10 mg/kg/day from GD 6 through postpartum Day 20 resulted in an increased duration of gestation, increased number of resorptions, decreased numbers of pups born, decreased postnatal survival and decreased pup body weights at 10 mg/kg/day (approximately 1.5-fold the exposure at the MRHD based on AUC). Lower mean body weights, body weight gains and food consumption persisted through the postweaning period. A NOAEL for fetal pre- and postnatal development was determined to be 5 mg/kg/day (0.7-fold the exposure at the MRHD based on AUC).

8.2 Lactation

Risk Summary

There are no data on the presence of venglustat in human milk, the effects on the breastfed infant, or the effects on milk production. Venglustat is present in animal milk *(see Data)*. When a drug is present in animal milk, it is likely that the drug will be present in human milk.

Nonclinical studies in juvenile rats have shown lens degeneration at clinically relevant exposure levels of venglustat. The clinical relevance is uncertain *[see Warnings and Precautions (5.2)]*.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for INFILBRAY, and any potential adverse effects on the breastfed child from INFILBRAY or from the underlying maternal condition. If the mother chooses to breastfeed during treatment with INFILBRAY, consider periodic ophthalmologic examinations in the breastfed infant.

Data

Milk excretion was assessed in lactating rats after a single oral dose of radiolabeled venglustat (10 mg/kg). Total radioactivity reached maximum concentrations in milk and plasma at 2 hours post-dose, with milk-to-plasma ratios of 0.85–0.95 over time. Nursing pups showed increasing gastrointestinal concentrations of radioactivity, with highest levels in pup tissues at 24 hours post-dose.

8.3 Females and Males of Reproductive Potential

Based on animal studies, venglustat may cause fetal harm when administered to pregnant women *[see Use in Specific Populations (8.1)]*.

Pregnancy Testing

Verify the pregnancy status of females of reproductive potential prior to starting treatment with INFILBRAY *[see Use in Specific Populations (8.1)]*.

Contraception

Females

Advise females of reproductive potential to use effective contraception during treatment with INFILBRAY and for 11 days after the last dose of INFILBRAY.

8.4 Pediatric Use

The safety and effectiveness of INFILBRAY for the treatment of neurological manifestations of GD3 have been established in pediatric patients weighing 15 kg and above. Use of INFILBRAY for this indication is supported by evidence from an adequate and well-controlled study in patients with GD3, which included 19 pediatric patients aged 12 to 17 years, and by additional pharmacokinetic data in 13 pediatric patients aged 2 to 17 years from an unapproved population *[see Adverse Reactions (6.1), Clinical Pharmacology (12.3), and Clinical Studies (14)]*.

The safety and effectiveness of INFILBRAY have not been established in pediatric patients weighing less than 15 kg.

Nonclinical findings suggest that use of INFILBRAY in pediatric patients has the potential for ocular lens degeneration *[see Warnings and Precautions (5.2)]*, decreased growth, and delayed puberty or sexual development in males *(see Juvenile Animal Toxicity Data)*.

Juvenile Animal Toxicity Data

In a juvenile toxicity study in male and female rats, oral venglustat was administered daily at 5, 15, or 45 mg/kg/day from postnatal day (PND) 22 to 91 of age (equivalent to human age ≥2 years). Decreased body weight gain was observed in males and females at 45 mg/kg/day (8- and 6-fold the exposure at the MRHD respectively based on AUC), but of greater severity in females and associated with reduced long bone growth. Lens degeneration was observed at 45 mg/kg/day (male) and 15 mg/kg/day (female) after 12 weeks (8- and 4-fold the exposure at the MRHD based on AUC) and was not apparent in a subset of recovery animals. In males, degeneration of testicular germinal epithelium was observed following 45 mg/kg/day venglustat and did not reverse following a 12-week recovery period. The NOAELs were considered to be 15 mg/kg/day (male) and 5 mg/kg/day (female), representing approximately 1.7-fold and 0.6-fold the exposure in GD3 patients receiving 15 mg, respectively.

In a second juvenile toxicity study in male rats only, juvenile rats were administered 45 mg/kg/day of venglustat at intervals beginning at PND 22 to 90, PND 22 to 50 and PND 35 to 63. Venglustat dosing beginning at PND 22, but not PND 35 resulted in a delay in the mean age of attaining balanopreputial separation, degeneration/atrophy of the seminiferous tubule of the testis, cellular debris and decreased sperm in the epididymis, and mixed cell inflammation of coagulating glands. These findings suggest the potential for delayed sexual development with early childhood exposure to venglustat. A NOAEL was established at 15 mg/kg/day, corresponding to 1.8-fold the MRHD based on AUC. These findings in the testes, epididymis and coagulating glands were not reversible following an 18-week recovery period; however, they did not impair eventual mating or fertility of these male rats.

8.5 Geriatric Use

Clinical studies of INFILBRAY did not include any subjects 65 years of age and older to determine whether they respond differently from younger adult patients.

There are no clinically meaningful differences in the pharmacokinetics of venglustat in adults aged 65 years and older compared to younger adults *[see Clinical Pharmacology (12.3)]*.

8.6 Renal Impairment

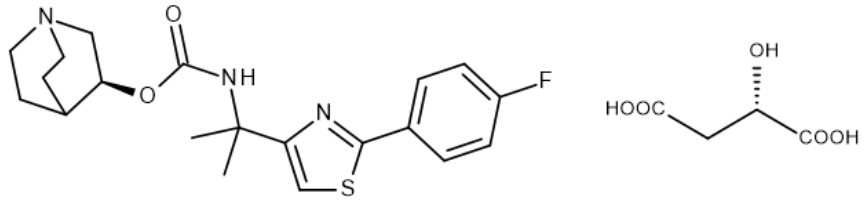
The recommended INFILBRAY dosage in adults with renal impairment and an eGFR greater than or equal to 30 mL/min is the same as that for adults without renal impairment *[see Dosage and Administration (2.2)]*. The recommended INFILBRAY dosage in adults with an eGFR less than 30 mL/min is lower than the recommended dosage in adults without renal impairment *[see Dosage and Administration (2.4)]*.

Plasma concentrations of venglustat increased in adults with an eGFR less than 30 mL/min *[see Clinical Pharmacology (12.3)]*.

The recommended INFILBRAY dosage in pediatric patients with renal impairment and an eGFR greater than or equal to 30 mL/min/1.73m^2 is the same as that for pediatric patients without renal impairment *[see Dosage and Administration (2.3)]*. No data are available to establish a dosage recommendation in pediatric patients with an eGFR less than 30 mL/min/1.73m^2.

11 DESCRIPTION

INFILBRAY (venglustat) tablets contain venglustat malate, which is a glucosylceramide synthase inhibitor that resembles the ceramide substrate for the enzyme, with the chemical name (2S)-2-hydroxybutanedioic acid - (3S)-1-azabicyclo[2.2.2]oct-3-yl {2-[2-(4-fluorophenyl)-1,3-thiazol-4-yl]propan-2-yl}carbamate (1:1). Its relative molecular mass is 523.59 for the salt form and 389.50 for the free base. The empirical formula is $C_{20}H_{24}FN_3O_2S$, $C_4H_6O_5$ with the following chemical structure:



Each tablet of INFILBRAY for oral use contains 6 mg or 15 mg of venglustat (equivalent to 8 mg or 20 mg of venglustat malate, respectively) and the following 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.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Type 3 Gaucher disease (GD3) is characterized by a deficiency of β-glucocerebrosidase activity, which results in accumulation of glucosylceramide (GL-1) and glucosylsphingosine (lyso-GL-1) in various tissues. Venglustat is an inhibitor of glucosylceramide synthase (GCS) (IC_{50} = 23 ng/mL) and crosses the blood-brain barrier. Venglustat acts as a substrate reduction therapy by

decreasing the synthesis of GL-1, a central building block for more complex glycosphingolipids (GSLs) such as globotriaosylceramide (GL-3).

12.2 Pharmacodynamics

Patients with GD3 have elevated levels of GL-1 and lyso-GL-1. The effect of INFILBRAY on GL-1 and lyso-GL-1 in plasma and cerebrospinal fluid (CSF) was assessed in adult and pediatric patients 12 years of age and older with GD3 who were previously treated with enzyme replacement therapy (ERT) *[see Clinical Studies (14)]*. The least squares (LS) mean (standard error (SE)) GL-1 concentration in plasma and CSF reduced by 73.1% (4.0%) and 64.3% (7.9%) respectively, and the LS mean (SE) lyso-GL-1 concentration in plasma and CSF reduced by 15.2% (8.9%) and 57.6% (10.2%), respectively, at Week 52 following treatment with INFILBRAY compared to baseline.

Cardiac Electrophysiology

At the recommended dosages, INFILBRAY is not likely to prolong the QTc interval to any clinically relevant extent.

12.3 Pharmacokinetics

In adults with GD3 who received 15 mg once daily, the geometric mean [coefficient of variation (CV%)] maximum plasma venglustat concentration (C_{max}) and area under the plasma concentration-time curve (AUC) at steady state were 150 ng/mL (34%) and 2610 ng*h/mL (33%), respectively. Venglustat C_{max} and AUC increase in an approximately dose proportional manner from 4 to 15 mg once daily. Steady-state is achieved within approximately 10 days, and accumulation is about 2-fold.

Absorption

The median time to reach maximum plasma venglustat concentrations (T_{max}) was between 2.5 to 6 hours after oral administration. The absolute bioavailability of venglustat following oral administration has not been determined.

Effect of Food

No clinically significant differences in venglustat pharmacokinetics were observed following a single oral administration of 15 mg venglustat with a high-fat meal containing 815 calories (52% fat, 33% carbohydrates, and 15% protein) in healthy adult subjects.

Distribution

Approximately 82% of venglustat is bound to human plasma proteins. The mean apparent volume of distribution of venglustat is 290 L. Venglustat was measured in CSF with CSF-to-plasma concentration ratio of 0.05.

Elimination

Metabolism

Venglustat undergoes extensive metabolism mainly through oxidative pathways and to a minor extent through direct glucuronidation. Metabolism occurs primarily via CYP3A, with a minor contribution from CYP2D6. M2 (N-oxide derivative) is a major circulating metabolite which does not contribute to the pharmacological activity of venglustat.

Excretion

In a mass balance study in healthy male subjects, following oral administration of 15 mg [^{14}C]-venglustat, approximately 83% of the total radiolabeled dose was recovered in urine and 12% of the total radiolabeled dose was recovered in feces within 14 days post-dose. The mean (standard deviation) apparent systemic clearance of venglustat is 6.1 (2.1) L/h, with renal clearance accounting for about 30% of the total clearance. The mean terminal half-life of venglustat is approximately 32 hours.

Specific Populations

Following administration of the approved recommended dosage *[see Dosage and Administration (2.2, 2.3)]*, there are no clinically meaningful differences in the pharmacokinetics of venglustat based on age (2 to 79 years), sex, ethnicity (Hispanic/Latino or not Hispanic/Latino), race (White, Asian, or Black or African American), or mild to moderate hepatic impairment (Child-Pugh A or B, respectively).

The impact of severe hepatic impairment (Child-Pugh C) on the pharmacokinetics of venglustat is unknown.

Pediatric Patients

The pharmacokinetics of venglustat were studied in pediatric patients with GD3 aged 12 years and older and in an unapproved population of pediatric patients aged 2 years and older. Following administration of the approved recommended dosage *[see Dosage and Administration (2.3)]*, venglustat exposure in pediatric patients weighing 15 kg and above is expected to be comparable to that of adults with GD3 who receive 15 mg once daily.

Patients with Renal Impairment

The pharmacokinetics of venglustat in adults with mild (eGFR 60 mL/min to <90 mL/min), moderate (eGFR 30 mL/min to <60 mL/min), or severe (eGFR <30 mL/min) renal impairment were compared to healthy subjects with normal renal function following administration of a single oral dose of INFILBRAY 15 mg *[see Use in Specific Populations (8.6)]*. There were no clinically significant differences in the pharmacokinetics of venglustat in adults with mild or moderate renal impairment compared to those with normal renal function. Venglustat AUC was estimated to be approximately 59% higher in adults with severe renal impairment compared to those with normal renal function *[see Dosage and Administration (2.4)*].

Drug Interaction Studies

Clinical Studies and Model-Informed Approaches

CYP3A Inhibitors

Venglustat is a CYP3A substrate. With coadministration of a single oral dose of 15 mg venglustat following 100 mg itraconazole (a strong CYP3A inhibitor) twice daily for five days, AUC of venglustat was increased by 103% as compared to venglustat administered alone in healthy subjects *[see Drug Interactions (7)]*.

CYP3A Inducers

Coadministration of steady-state venglustat with multiple-dose rifampicin (a strong CYP3A inducer) is predicted to decrease venglustat C_{max} and AUC by 52% and 69%, respectively, as compared to venglustat administered alone in healthy subjects *[see Drug Interactions (7)]*.

Coadministration of steady-state venglustat with multiple-dose phenobarbital or efavirenz (moderate CYP3A inducers) is predicted to decrease venglustat C_{max} and AUC by 39% to 47% and 53% to 61%, respectively, as compared to venglustat administered alone in healthy subjects *[see Drug Interactions (7)]*.

In Vitro Studies

CYP enzymes: Venglustat is a CYP3A substrate. Venglustat does not inhibit or induce CYP1A2, CYP2A6, CYP2B6, CYP2C8, CYP2C9, CYP2C19, CYP2D6, CYP2E1, CYP2J2 or CYP3A4 at clinically relevant concentrations.

Transporter systems: Venglustat does not inhibit P-glycoprotein (P-gp), breast cancer resistance protein (BCRP), organic anion transporting polypeptides (OATP1B1 and OATP1B3), organic cation transporters (OCT1 and OCT2), multidrug and toxin extrusion transporters (MATE2-K), or the bile salt export pump (BSEP). Venglustat is an inhibitor of MATE1, but its clinical significance is unknown.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

In a 2-year carcinogenicity study in male and female rats, oral doses of venglustat increased the incidence of squamous cell papilloma in the skin/subcutis at 20 mg/kg/day (11-fold the exposure at the MRHD based on AUC) and increased the incidence of endometrial stromal polyp in the uterus at doses ≥2 mg/kg/day (0.4-fold the exposure at the MRHD based on AUC). No drug-related neoplastic findings were observed in male rats at doses up to 6.6-fold the exposure at the MRHD based on AUC.

In a 6-month carcinogenicity study in male and female Tg.rasH2 mice, there was no evidence of drug-related carcinogenicity at oral doses up to 60 mg/kg/day venglustat (16-fold the exposure at the MRHD based on body surface).

Mutagenesis

Venglustat did not show any potential for mutagenic or clastogenic effects in an *in vitro* bacterial mutation assay (Ames test in *Salmonella*), an *in vitro* chromosomal aberration test using cultured human lymphocytes, and an *in vivo* rat bone marrow micronucleus test.

Impairment of Fertility

In fertility and early embryonic development studies conducted in male and female rats, venglustat had no effect on fertility and reproductive performance up to 20 mg/kg/day in females and 30 mg/kg/day in males.

13.2 Animal Toxicology and/or Pharmacology

Repeat dose toxicity studies were conducted in rats and dogs. The primary target organs of toxicity following the administration of venglustat for up to 6 months in rats and 9 months in dogs included the eyes (rats), immune system (rats) and testis (rats).

Eye

In adult female rats, daily oral administration of venglustat for 26 weeks resulted in partially reversible corneal thickening with lens degeneration at 20 mg/kg/day (10-fold the exposure at the MRHD based on AUC), with a NOAEL of 10 mg/kg/day (3-fold the exposure at the MRHD based on AUC) *[see Warnings and Precautions (5.2)]*.

Immune System

In adult male and female rats and dogs, chronic oral administration of venglustat resulted in lymphoid tissue atrophy across multiple organs, including thymus, spleen and lymph nodes at doses ≥20 mg/kg/day in each species. A NOAEL was determined to be 10 mg/kg/day, which represents 1.7- to 3.7-fold the exposure at the MRHD based on AUC in rats, and 8.5- to 13.9-fold the exposure at the MRHD based on AUC in dogs.

Reproductive Organs

In adult male rats, daily oral administration of venglustat for 26 weeks did not result in testicular or epididymal toxicities, nor the differences in sperm count, morphology, motility, or daily sperm production that were observed in juvenile studies *[see Use in Specific Populations (8.4)]*. A NOAEL for reproductive organ toxicity was considered to be 20 mg/kg/day (10-fold the exposure at the MRHD based on AUC).

14 CLINICAL STUDIES

The efficacy of INFILBRAY was evaluated in a randomized, double-blind, double-dummy, active-controlled, multicenter clinical study (Study 1; NCT05222906) in patients aged 12 years and older with Type 3 Gaucher disease (GD3), previously treated with enzyme replacement therapy (ERT). Patients were eligible to enroll if they had neurological manifestations, had been treated with ERT for at least 3 years and clinically stable for at least one year in terms of hemoglobin, platelet count, liver volume, and spleen volume. The study included a double-blind primary analysis treatment period (Day 1 to Week 52) and an extended treatment period (post-Week 52 through study completion). Following the primary analysis period at Week 52, patients originally randomized to imiglucerase received INFILBRAY, and patients originally randomized to INFILBRAY continued to receive INFILBRAY.

A total of 43 patients were randomized in a 1:1 ratio to receive INFILBRAY tablets orally once daily plus intravenous placebo, or intravenous imiglucerase every two weeks plus oral placebo, for a total of 52 weeks during the primary analysis period. Patients were stratified by age group (12 to 17 years; 18 years and older). For adult patients aged 18 years and older, all received 15 mg once daily. For pediatric patients aged 12 to 17 years old, the dosage of INFILBRAY was weight-based. Pediatric patients weighing 50 kg or more received 15 mg once daily, and those weighing 30 kg to less than 50 kg received 12 mg once daily.

At baseline, median age was 19 years (range: 12 to 44 years); 56% were 18 years and older, and 44% were 12 to 17 years old. Overall, 49% were male and 51% were female. Patients were White (61%), Asian (28%), American Indian or Alaska Native (5%), of multiple ethnic origins (2%) or not reported (5%). Hispanic or Latino ethnicity was 9%. Median length of ERT treatment prior to enrollment was 14 years, ranging from 3 to 26 years.

The efficacy of INFILBRAY was evaluated using multiple endpoints composed of the change from baseline to Week 52 in the modified Scale for the Assessment and Rating of Ataxia (SARA) (4-item SARA score) and the change from baseline to Week 52 in the Repeatable Battery for the Assessment of Neuropsychological Status (RBANS) total scale index score. The modified SARA (4-item SARA score) evaluated four domains including gait, stance, sitting, and speech disturbance (range: 0 to 16, lower scores denote better neurological function), and the RBANS evaluated five domains including immediate memory, visuospatial/constructional abilities, language, attention, and delayed memory (range: 40 to 160, higher scores denote better neurological function).

INFILBRAY demonstrated improvements in neurological manifestations over imiglucerase (Table 6). The global test of multiple neurological endpoints demonstrated statistically significant superiority. The estimated mean treatment difference was 8.32 (95% CI: 0.75, 15.89) on the RBANS score and -0.49 (-1.29, 0.32) for the modified SARA (4-item SARA score).

Table 6: Change in 4-item SARA Score and RBANS from Baseline to Week 52 in Patients 12 Years of Age and Older with GD3 in Study 1*

	INFILBRAY (n = 21)	Imiglucerase (n = 22)	Treatment Difference (95% CI)
4-item SARA Score			
Mean Baseline (SD)	2.19 (1.47)	3.18 (2.38)	
Mean Week 52 (SD)	1.71 (1.52)	2.81 (2.32)	
Mean Change Week 52 (SD)	-0.48 (0.87)	-0.14 (1.59)	
§LS Mean Change Week 52 (SE)	-0.56 (0.28)	-0.08 (0.28)	-0.49 (-1.29, 0.32)
RBANS			
Mean Baseline (SD)	78.57 (18.28)	68.36 (20.87)	
Mean Week 52 (SD)	80.55 (19.24)	66.14 (16.79)	
Mean Change Week 52 (SD)	2.05 (14.81)	-3.52 (11.34)	
§LS Mean Change Week 52 (SE)	3.69 (2.65)	-4.63 (2.57)	8.32 (0.75, 15.89)

LS: least squares; SD: standard deviation; SE: standard error

*SARA = Scale for Assessment and Rating of Ataxia. Modified SARA from 0 to 4 in each domain and 0 to 16 in total (4-item); RBANS = Repeatable Battery for the Assessment of Neuropsychological Status.

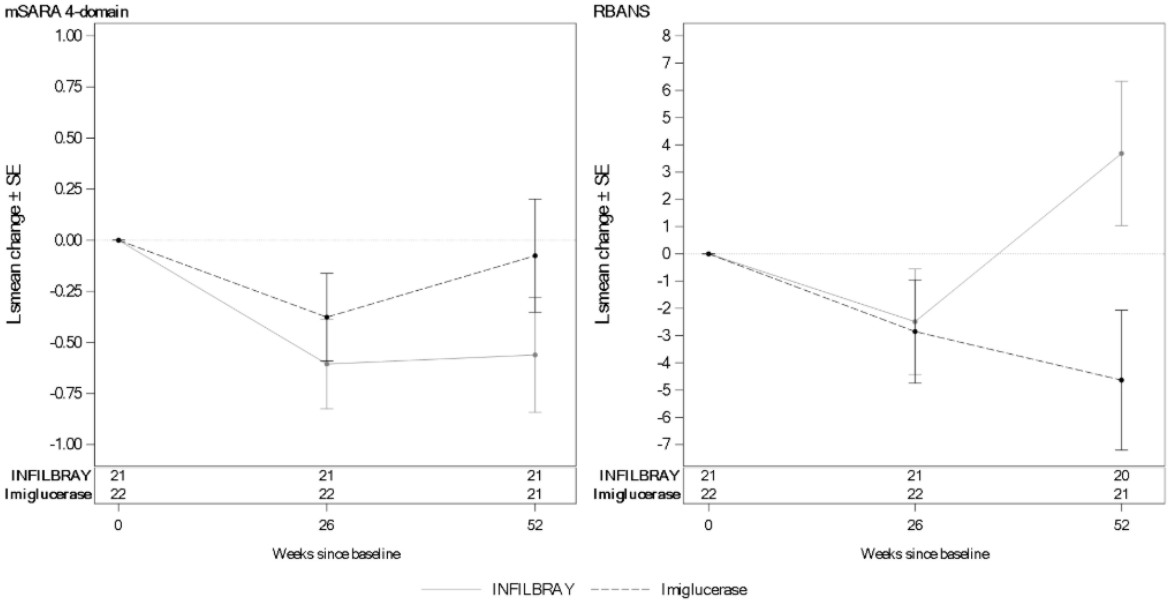
§ Estimated from a mixed-effects model for repeated measures (MMRM). An O'Brien ordinary least squares (OLS) global test of modified SARA 4-domain and RBANS had a p-value of 0.0137.

The MMRM for change from baseline at Weeks 26 and 52 included fixed effects of treatment, randomization stratum (age <18 years vs. ≥ 18 years), visit (Week 26, 52), treatment-by-visit and stratum-by-visit interactions, with baseline and baseline-by-visit as covariates.

Lower SARA scores and higher RBANS scores indicate improvement in neurological function, respectively.

Figure 1 shows change from baseline over time in LS mean modified SARA (4-item SARA score) and RBANS total score through the 52-week primary analysis treatment period in the INFILBRAY arm versus the imiglucerase arm.

Figure 1 – Modified SARA (4-item SARA Score) and RBANS Total Scale Index Score: Plot of LS Mean (+/- SE) Change from Baseline Across Analysis Visits up to Week 52 in Patients 12 Years of Age and Older with GD3 (Study 1)*



*SARA = Scale for Assessment and Rating of Ataxia. Modified SARA from 0 to 4 in each domain and 0 to 16 in total (4-item); lower scores indicate improvement. RBANS = Repeatable Battery for the Assessment of Neuropsychological Status. Total Scale Index Score ranges from 40 (worse cognition lowest score) to 160 (best cognition highest score); higher scores indicate improvement. LS = Least Squares, SE = standard error

16 HOW SUPPLIED/STORAGE AND HANDLING

INFILBRAY tablets are packaged in blister cards and supplied in child-resistant cartons as follows:

Strength of Venglustat	Description	Package Configuration	NDC
6 mg	White to off-white, oblong, apricot-flavored tablet, debossed with "6" on one side.	Carton containing 28 tablets (1 blister card of 28 tablets)	58468-2006-1
15 mg	White to off-white, round, apricot-flavored tablet, debossed with "15" on one side.	Carton containing 28 tablets (1 blister card of 28 tablets)	58468-2015-1

Store from 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F and 86°F) [see USP Controlled Room Temperature]. Store in the original package to protect from moisture. Keep in original package until immediately before administration.

17 PATIENT COUNSELING INFORMATION

Advise patients and/or caregivers to read the FDA-approved patient labeling (Patient Information).

Suicidal Ideation and Behavior

Inform patients or caregivers of the potential for behavioral and mood changes and advise them to seek medical attention for manifestations of suicidal ideation and behavior, new onset or worsening depression, or other mood changes *[see Warnings and Precautions (5.1) and Adverse Reactions (6.1)]*.

Lens Opacification in Pediatric Patients

Inform pediatric patients and caregivers that lens opacification may occur during chronic treatment with INFILBRAY. Advise pediatric patients and caregivers that ophthalmological assessments before and once a year during treatment will be needed and to report any changes in vision to their healthcare provider *[see Warnings and Precautions (5.2)]*.

Pregnancy

Advise pregnant women and females of reproductive potential that, based on animal data, exposure to INFILBRAY during pregnancy may result in fetal harm. Advise females to inform their healthcare provider of a known or suspected pregnancy *[see Warnings and Precautions (5.3) and Use in Specific Populations (8.1)]*.

Advise females of reproductive potential to use effective contraception during treatment and for 11 days after the last dose *[see Use in Specific Populations (8.3)]*.

Administration Instructions

Inform patients to take INFILBRAY orally once daily with or without food.

Advise patients to swallow the tablets whole, chew the tablets and then swallow, or crush and mix the tablets with liquids or soft foods. Inform patients to take the tablets within 30 minutes after mixing, and not to mix with juice containing grapefruit or Seville oranges *[see Dosage and Administration (2.6)]*.

Missed or Vomited Dose

Inform patients if a dose of INFILBRAY is missed by more than 12 hours, skip the dose and take the next dose at the regularly scheduled time.

Inform patients that if vomiting occurs after taking a dose of INFILBRAY, do not take an additional dose and take the next dose at the regularly scheduled time.

Advise patients not to double the next scheduled dose if a dose is skipped or is vomited *[see Dosage and Administration (2.7)]*.

Manufactured by:

Genzyme Corporation
450 Water Street
Cambridge, MA 02141
A SANOFI COMPANY

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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