DAYBUE- trofinetide solution
DAYBUE STIX- trofinetide for solution
Acadia Pharmaceuticals Inc.

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use DAYBUE or DAYBUE STIX safely and effectively. See full prescribing information for DAYBUE and DAYBUE STIX.

DAYBUE® (trofinetide) oral solution
DAYBUE® STIX (trofinetide) for oral solution
Initial U.S. Approval: 2023

RECENT MAJOR CHANGES

Dosage and Administration (2.1, 2.2, 2.3, 2.6)	12/2025

INDICATIONS AND USAGE

DAYBUE and DAYBUE STIX are indicated for the treatment of Rett syndrome in adults and pediatric patients 2 years of age and older. (1)

DOSAGE AND ADMINISTRATION

- Recommended dosage is twice daily, morning and evening, according to patient weight. DAYBUE or DAYBUE STIX can be given with or without food. (2.1)

Patient Weight	Recommended Dosage
9 kg to less than 12 kg	5,000 mg twice daily
12 kg to less than 20 kg	6,000 mg twice daily
20 kg to less than 35 kg	8,000 mg twice daily
35 kg to less than 50 kg	10,000 mg twice daily
50 kg or more	12,000 mg twice daily

- Can be given orally or via gastrostomy (G) tube; doses administered via gastrojejunal (GJ) tubes must be administered through the G-port. (2.1)
- See Full Prescribing Information for instruction on dissolving DAYBUE STIX for oral solution powder. (2.3)
- See Full Prescribing Information for dosage recommendations in patients with renal impairment. (2.6, 8.6)

DOSAGE FORMS AND STRENGTHS

- Oral solution: 200 mg/mL (3)
- For oral solution: 5,000 mg, 6,000 mg, or 8,000 mg per packet (3)

CONTRAINDICATIONS

None. (4)

WARNINGS AND PRECAUTIONS

- Diarrhea: Most patients experience diarrhea during treatment with DAYBUE. Advise patients to stop laxatives before starting DAYBUE or DAYBUE STIX. If diarrhea occurs, patients should start antidiarrheal treatment, increase oral fluids, and notify their healthcare provider. Interrupt, reduce dose, or discontinue DAYBUE or DAYBUE STIX if severe diarrhea occurs or if dehydration is suspected. (2.4, 5.1)
- Weight Loss: Weight loss may occur in patients treated with DAYBUE or DAYBUE STIX. Monitor weight and interrupt, reduce dose, or discontinue DAYBUE or DAYBUE STIX if significant weight loss occurs. (2.4, 5.2)
- Vomiting: Aspiration and aspiration pneumonia have occurred after vomiting in patients treated with DAYBUE. Interrupt, reduce dose, or discontinue DAYBUE or DAYBUE STIX if vomiting is severe or occurs despite medical management. (2.5, 5.3)

ADVERSE REACTIONS

The most common adverse reactions (that occurred in at least 10% of DAYBUE-treated patients and at

least 2% greater than in placebo) were diarrhea and vomiting. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Acadia Pharmaceuticals Inc. at 1-844-422-2342 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

- Orally administered CYP3A and/or P-gp sensitive substrates for which a small change in substrate plasma concentration may lead to serious adverse reactions: closely monitor for adverse reactions with concomitant use. (7.1)

USE IN SPECIFIC POPULATIONS

Severe renal impairment: DAYBUE and DAYBUE STIX are not recommended. (8.6)

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

Revised: 3/2026

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

DAYBUE and DAYBUE STIX are indicated for the treatment of Rett syndrome in adults and pediatric patients 2 years of age and older.

2 DOSAGE AND ADMINISTRATION

2.1 Recommended Dosage

The recommended dosage of DAYBUE or DAYBUE STIX is based on patient weight as shown in **Table 1**. Administer DAYBUE or DAYBUE STIX orally or via gastrostomy (G) tube twice daily, in the morning and evening, with or without food. Doses administered via gastrojejunal (GJ) tubes must be administered through the G-port.

Table 1 Recommended Dosage of DAYBUE or DAYBUE STIX in Patients 2 Years of Age and Older

Patient Weight	Recommended Dosage
9 kg to less than 12 kg	5,000 mg twice daily
12 kg to less than 20 kg	6,000 mg twice daily
20 kg to less than 35 kg	8,000 mg twice daily
35 kg to less than 50 kg	10,000 mg twice daily
50 kg or more	12,000 mg twice daily

2.2 DAYBUE Oral Solution Preparation

Table 2 includes the volume of DAYBUE oral solution to administer for the corresponding recommended dosage *[see Dosage and Administration (2.1, 2.6)]*. A calibrated measuring device, such as an oral syringe or oral dosing cup, should be obtained from the pharmacy to measure and deliver the prescribed dose accurately. A household measuring cup, teaspoon, or tablespoon is not an adequate measuring device.

Table 2 Recommended Volume of DAYBUE Oral Solution for Administration

	DAYBUE Oral Solution

Dosage	DAYBUE Oral Solution Volume
2,500 mg twice daily*	12.5 mL twice daily
3,000 mg twice daily*	15 mL twice daily
4,000 mg twice daily*	20 mL twice daily
5,000 mg twice daily	25 mL twice daily
6,000 mg twice daily	30 mL twice daily
8,000 mg twice daily	40 mL twice daily
10,000 mg twice daily	50 mL twice daily
12,000 mg twice daily	60 mL twice daily

* Dosage for patients with moderate renal impairment *[see Dosage and Administration (2.6)]*

Discard any unused DAYBUE oral solution after 14 days of first opening the bottle *[see How Supplied/Storage and Handling (16.2)]*.

2.3 DAYBUE STIX for Oral Solution Preparation

Prior to administration, DAYBUE STIX for oral solution powder must be dissolved in a cold to room temperature water or water-based beverage (juice, tea, lemonade, limeade, or liquid hydration).

Preparation of DAYBUE STIX

1. Determine the correct dosage as shown in **Table 1** or **Table 4** (for patients with moderate renal impairment).
2. Select the appropriate packet strength and number of packets required for each dose, as shown in **Table 3**.
3. Determine the appropriate volume of liquid within the recommended volume range as shown in **Table 3**, based on individual patient factors (e.g., age, palatability).
4. Measure the volume of liquid determined in Step 3 by using a calibrated measuring device obtained from the pharmacy.
5. Empty the entire contents of the DAYBUE STIX packet(s) into the measured liquid. Do not attempt to use partial packets to prepare a dose.
6. Stir until the powder is completely dissolved.
7. Administer the prepared oral solution immediately; do not store for future use.
8. Discard any prepared oral solution that is not immediately administered.

Table 3 Preparation Instructions for DAYBUE STIX for Oral Solution Powder

Dose	DAYBUE STIX Packet(s) Needed to Prepare Each Dose	Volume of Liquid Required to Dissolve Entire Dose*, †
5,000 mg	One 5,000 mg packet	15 mL to 60 mL
6,000 mg	One 6,000 mg packet	15 mL to 60 mL
	One 8,000 mg	

8,000 mg	One 8,000 mg packet	25 mL to 120 mL
10,000 mg	Two 5,000 mg packets	30 mL to 120 mL (each packet requires 15 mL to 60 mL)
12,000 mg	Two 6,000 mg packets	30 mL to 120 mL (each packet requires 15 mL to 60 mL)

* Liquid types include water or water-based beverage.
† Volume should be selected within the recommended range based on individual patient factors.

2.4 Dose Modification for Diarrhea or Weight Loss

Advise patients to stop laxatives before starting DAYBUE or DAYBUE STIX. Interrupt, reduce dose, or discontinue DAYBUE or DAYBUE STIX if severe diarrhea occurs, if dehydration is suspected, or if significant weight loss occurs *[see Warnings and Precautions (5.1, 5.2)].*

2.5 Dose Modification for Vomiting After Administration

If vomiting occurs after DAYBUE or DAYBUE STIX administration, an additional dose should not be taken. Instead, continue with the next scheduled dose. Interrupt, reduce dose, or discontinue DAYBUE or DAYBUE STIX if vomiting is severe or occurs despite medical management *[see Warnings and Precautions (5.3)]*.

2.6 Dosage Recommendations in Patients with Renal Impairment

No dosage adjustment is recommended for patients with mild renal impairment (estimated glomerular filtration rate [eGFR] 60 to 89 mL/min for adult patients or 60 to 89 mL/min/1.73 m^2 for pediatric patients). The recommended dosage of DAYBUE or DAYBUE STIX for patients with moderate renal impairment (eGFR 30 to 59 mL/min for adult patients or 30 to 59 mL/min/1.73 m^2 for pediatric patients) is described in **Table 4** *[see Use in Specific Populations (8.6), Clinical Pharmacology (12.3)].* DAYBUE and DAYBUE STIX are not recommended for patients with severe renal impairment (eGFR less than 30 mL/min for adult patients or less than 30 mL/min/1.73 m^2 for pediatric patients).

For patients with moderate renal impairment who require a dose less than 5,000 mg, DAYBUE oral solution is recommended. Do not attempt to use partial packets of DAYBUE STIX to prepare a dose.

Table 4 Recommended Dosage of DAYBUE or DAYBUE STIX in Patients with Moderate Renal Impairment

Patient Weight	Recommended Dosage
9 kg to less than 12 kg	2,500 mg twice daily*
12 kg to less than 20 kg	3,000 mg twice daily*
20 kg to less than 35 kg	4,000 mg twice daily*
35 kg to less than 50 kg	5,000 mg twice daily
50 kg or more	6,000 mg twice daily

* Use DAYBUE oral solution to administer this dosage.

2.7 Missed Dose

If a dose of DAYBUE or DAYBUE STIX is missed, the next dose should be taken as scheduled. Doses should not be doubled.

3 DOSAGE FORMS AND STRENGTHS

Oral solution: 200 mg/mL of a pink to red, strawberry flavored solution.

For oral solution: 5,000 mg, 6,000 mg, or 8,000 mg of white, off-white to pinkish powder with strawberry flavor, packaged in individual packets.

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Diarrhea

In Study 1 *[see Clinical Studies (14)]* and in long-term studies, 85% of patients treated with DAYBUE experienced diarrhea. In those treated with DAYBUE, 49% either had persistent diarrhea or recurrence after resolution despite dose interruptions, reductions, or concomitant antidiarrheal therapy. Diarrhea severity was of mild or moderate severity in 96% of cases. In Study 1, antidiarrheal medication was used in 51% of patients treated with DAYBUE.

Advise patients to stop laxatives before starting DAYBUE or DAYBUE STIX. If diarrhea occurs, patients should notify their healthcare provider, consider starting antidiarrheal treatment, and monitor hydration status and increase oral fluids, if needed. Interrupt, reduce dose, or discontinue DAYBUE or DAYBUE STIX if severe diarrhea occurs or if dehydration is suspected *[see Dosage and Administration (2.4)]*.

5.2 Weight Loss

In Study 1, 12% of patients treated with DAYBUE experienced weight loss of greater than 7% from baseline, compared to 4% of patients who received placebo. In long-term studies, 2.2% of patients discontinued treatment with DAYBUE due to weight loss.

Monitor weight and interrupt, reduce dose, or discontinue DAYBUE or DAYBUE STIX if significant weight loss occurs *[see Dosage and Administration (2.4)]*.

5.3 Vomiting

In Study 1, vomiting occurred in 29% of patients treated with DAYBUE and in 12% of patients who received placebo *[see Adverse Reactions (6.1)].*

Patients with Rett syndrome are at risk for aspiration and aspiration pneumonia. Aspiration and aspiration pneumonia have been reported following vomiting in patients being treated with DAYBUE. Interrupt, reduce dose, or discontinue DAYBUE or DAYBUE STIX if vomiting is severe or occurs despite medical management *[see Dosage and*

Administration (2.5)].

6 ADVERSE REACTIONS

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

- Diarrhea *[see Warnings and Precautions (5.1)]*
- Weight Loss *[see Warnings and Precautions (5.2)]*
- Vomiting *[see Warnings and Precautions (5.3)]*

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.

In controlled and uncontrolled trials in patients with Rett syndrome, 260 patients ages 2 to 40 years were treated with DAYBUE, including 112 patients treated for more than 6 months, 92 patients treated for more than 1 year, and 44 patients treated for more than 2 years.

The safety of DAYBUE STIX has been established from an adequate, well-controlled study, and open-label studies of DAYBUE *[see Clinical Studies (14)]*. Below is a display of the adverse reactions of DAYBUE in these studies.

Adult and Pediatric Patients with Rett Syndrome 5 Years of Age and Older

The safety of DAYBUE was evaluated in a randomized, double-blind, placebo-controlled, 12-week study of patients with Rett syndrome (Study 1) *[see Clinical Studies (14)]*. In Study 1, 93 patients received DAYBUE and 94 patients received placebo. All patients were female, 92% were White, and the mean age was 11 years (range 5 to 20 years).

Adverse Reactions Leading to Discontinuation of Treatment

Eighteen patients (19%) receiving DAYBUE had adverse reactions that led to withdrawal from the study. The most common adverse reaction leading to discontinuation of treatment with DAYBUE was diarrhea (15%).

Common Adverse Reactions

Adverse reactions that occurred in Study 1 in at least 5% of patients treated with DAYBUE and were at least 2% more frequent than in patients on placebo are presented in **Table 5**.

Table 5 Adverse Reactions in at Least 5% of Patients Treated with DAYBUE and at Least 2% Greater than Placebo in Study 1

Adverse Reaction	DAYBUE (N=93) %	Placebo (N=94) %
Diarrhea	82	20
Vomiting	29	12
Fever	9	4

Seizure	9	6
Anxiety	8	1
Decreased appetite	8	2
Fatigue	8	2
Nasopharyngitis	5	1

Pediatric Patients with Rett Syndrome 2 to 4 Years of Age

In an open-label study in pediatric patients 2 to 4 years of age with Rett syndrome (N=15), a total of 13 patients received DAYBUE for at least 12 weeks and 10 patients received DAYBUE for at least 12 months. Adverse reactions in pediatric patients 2 to 4 years of age treated with DAYBUE were similar to those reported in adult and pediatric patients 5 years of age and older with Rett syndrome in Study 1.

6.2 Postmarketing Experience

The following adverse reactions have been identified during postapproval use of DAYBUE. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Aspiration and aspiration pneumonia secondary to vomiting *[see Warnings and Precautions (5.3)]*.

7 DRUG INTERACTIONS

7.1 Effect of DAYBUE and DAYBUE STIX on Other Drugs

CYP3A and/or P-gp Substrates

Closely monitor patients when DAYBUE or DAYBUE STIX is administered concomitantly with sensitive CYP3A and/or P-gp substrates where minimal increases in the plasma concentration of these substrates may lead to serious adverse reactions. Trofinetide, a weak inhibitor of CYP3A and an inhibitor of P-gp, increased the plasma concentrations of CYP3A and/or P-gp substrates *[see Clinical Pharmacology (12.3)]*, which may increase the risk of adverse reactions associated with these substrates.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no adequate data on the developmental risks associated with the use of DAYBUE or DAYBUE STIX in pregnant women. No adverse developmental effects were observed following oral administration of trofinetide to pregnant animals at doses associated with plasma exposures below those used clinically *[see Animal Data]*.

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. 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.

Data

Animal Data

Oral administration of trofinetide (0, 150, 450, or 1000 mg/kg twice daily; 0, 300, 900, or 2000 mg/kg/day) to pregnant rats during the period of organogenesis resulted in no adverse effects on embryofetal development. At the highest dose tested, plasma exposure (AUC) was less than that in humans at the maximum recommended human dose (MRHD) of 12,000 mg twice daily (24,000 mg/day).

Oral administration of trofinetide (0, 75, 150, or 300 mg/kg twice daily; 0, 150, 300, or 600 mg/kg/day) to pregnant rabbits during the period of organogenesis resulted in no adverse effects on embryofetal development. At the highest dose tested, plasma exposure (AUC) was less than that in humans at the MRHD.

Oral administration of trofinetide (0, 150, 450, or 1000 mg/kg twice daily; 0, 300, 900, or 2000 mg/kg/day) to rats throughout pregnancy and lactation resulted in no adverse effects on pre- and postnatal development. At the highest dose tested, plasma exposure (AUC) was less than that in humans at the MRHD.

8.2 Lactation

Risk Summary

There is no information regarding the presence of trofinetide or its metabolites in human milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for DAYBUE or DAYBUE STIX and any potential adverse effects on the breastfed infant from the treatment or from the underlying maternal condition.

8.4 Pediatric Use

The safety and effectiveness of DAYBUE and DAYBUE STIX for the treatment of Rett syndrome have been established in pediatric patients aged 2 years and older. The safety and effectiveness of DAYBUE for the treatment of Rett syndrome in pediatric patients 5 years of age and older was established in a randomized, double-blind, placebo-controlled, 12-week study (Study 1), which included 108 pediatric patients age 5 to less than 12 years of age and 47 pediatric patients age 12 to less than 17 years of age *[see Adverse Reactions (6.1) and Clinical Studies (14)].* Use of DAYBUE or DAYBUE STIX in patients 2 to 4 years of age is supported by evidence from Study 1 and pharmacokinetic and safety data in 15 pediatric patients 2 to 4 years of age treated with DAYBUE *[see Dosage and Administration (2.1), Adverse Reactions (6.1), Clinical Pharmacology (12.3), and Clinical Studies (14)]*.

Safety and effectiveness in pediatric patients less than 2 years of age have not been established.

Juvenile Animal Data

Oral administration of trofinetide (0, 150, 300, or 1000 mg/kg twice daily; 0, 300, 600, or 2000 mg/kg/day) to rats from postnatal day (PND) 13-14 through 28 weeks of age resulted in no adverse effects on growth or neurobehavioral function. Plasma exposures at the highest dose tested were similar to those in pediatric patients at

recommended doses.

Oral administration of trofinetide (0, 150, 300, or 1000 mg/kg twice daily; 0, 300, 600, or 2000 mg/kg/day) to juvenile rats for 10 weeks beginning on PND 13-14 resulted in no adverse effects on sexual maturation or reproductive function. Plasma exposures at the highest dose tested were similar to those in pediatric patients at recommended doses.

8.5 Geriatric Use

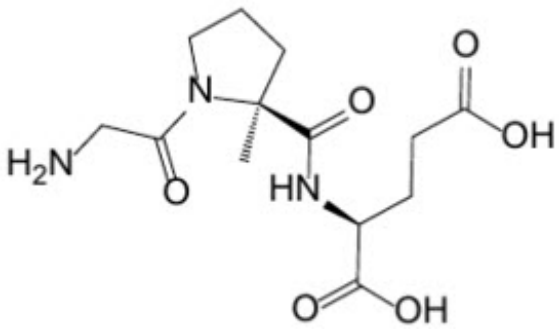
Clinical studies of DAYBUE did not include patients 65 years of age and older to determine whether or not they respond differently from younger patients. This drug is known to be substantially excreted by the kidney. Because elderly patients are more likely to have decreased renal function, it may be useful to monitor renal function.

8.6 Renal Impairment

Mild renal impairment is not expected to impact the exposure of trofinetide; therefore, dosage adjustment is not necessary. Dosage adjustment of DAYBUE or DAYBUE STIX is recommended in patients with moderate renal impairment (adult: eGFR 30 to 59 mL/min; pediatric: eGFR 30 to 59 mL/min/1.73 m^2) *[see Dosage and Administration (2.6), Clinical Pharmacology (12.3)]*. Administration of DAYBUE or DAYBUE STIX to patients with severe renal impairment (eGFR less than 30 mL/min for adults or less than 30 mL/min/1.73 m^2 for pediatrics) is not recommended.

11 DESCRIPTION

DAYBUE oral solution and DAYBUE STIX for oral solution contain the active moiety trofinetide. The chemical name of trofinetide is (2S)-2-{[(2S)-1-(2-aminoacetyl)-2-methylpyrrolidine-2-carbonyl]amino}pentanedioic acid (IUPAC). The molecular formula of trofinetide is $C_{13}H_{21}N_3O_6$ and its molecular weight is 315.33 g/mol. The chemical structure is shown below.



Trofinetide is a white to off-white solid and is freely soluble in water.

DAYBUE oral solution is pink to red in color and contains 1 g of trofinetide in each 5 mL of solution (200 mg/mL). The oral solution also contains FD&C Red No. 40, maltitol, methylparaben sodium, propylparaben sodium, purified water, strawberry flavor, and sucralose as inactive ingredients.

DAYBUE STIX for oral solution is a white, off-white to pinkish powder to be dissolved in a cold to room temperature water or water-based beverage before administration and

contains 5,000 mg, 6,000 mg, or 8,000 mg of trofinetide in each packet. The for oral solution powder contains natural strawberry flavor and sucralose as inactive ingredients.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

The mechanism by which trofinetide exerts therapeutic effects in patients with Rett syndrome is unknown.

12.2 Pharmacodynamics

Cardiac Electrophysiology

At the maximum recommended dose in healthy adult subjects, trofinetide does not prolong the QT interval to any clinically relevant extent.

12.3 Pharmacokinetics

DAYBUE STIX for oral solution demonstrated comparable bioavailability to DAYBUE oral solution in adult healthy subjects under fasted state.

Trofinetide exhibits linear kinetics with no time- or dose-dependent effect on pharmacokinetic parameters. Systemic exposure to trofinetide was dose-proportional across the studied dose range. Minimal to no accumulation was observed following multiple-dose administration.

Absorption

The time to maximum drug concentration (T_{max}) is about 2 to 3 hours after administration. Based on the mass balance study, at least 84% of the administered dose was absorbed following oral administration of 12,000 mg trofinetide.

Effect of Food

Coadministration of trofinetide with a high-fat meal had no impact on the total exposure ($AUC_{0\text{-}inf}$) of trofinetide and reduced the peak plasma concentration (C_{max}) by approximately 20% *[see Dosage and Administration (2.1)]*.

Distribution

Following oral administration, the apparent volume of distribution of trofinetide in adult healthy subjects was approximately 80 L. Trofinetide protein binding in human plasma is less than 6%.

Elimination

The effective elimination half-life of orally administered trofinetide in healthy subjects is about 1.5 hours.

Metabolism

Trofinetide is not significantly metabolized by CYP450 enzymes. Hepatic metabolism is not a significant route of trofinetide elimination.

Excretion

Trofinetide is primarily excreted unchanged (approximately 80% of the dose) in urine, with minor excretion in feces.

Specific Populations

Pediatric Patients

The drug exposure of trofinetide in pediatric patients ages 2 to 4 years of age is similar to children older than 4 years and adults when following the recommended dosage *[see Dosage and Administration (2.1)]*.

Patients with Renal Impairment

Based on population PK analysis of clinical trials data, patients with mild renal impairment (eGFR 60 to 89 mL/min/1.73 m^2) showed no significant impact on the exposure of trofinetide compared to patients with normal renal function. Based on a renal impairment study in adult subjects, the effect of moderate renal impairment (eGFR 30 to 59 mL/min) increases the exposure ($AUC_{0\text{-}inf}$) of trofinetide approximately 80% compared to patients with normal renal function administered the same dose *[see Dosage and Administration (2.6)]*. The effect of severe renal impairment on the exposure of trofinetide has not been investigated *[see Use in Specific Populations (8.6)]*.

Patients with Hepatic Impairment

The pharmacokinetics in patients with hepatic impairment have not been studied. However, hepatic impairment is not expected to impact the exposure of trofinetide because hepatic metabolism is not a significant route of trofinetide elimination.

Drug Interaction Studies

Clinical Studies

CYP3A and/or P-gp Substrates:

Coadministration of trofinetide 12,000 mg twice daily with 4 mg of loperamide (a moderately sensitive CYP3A substrate and a P-gp substrate) increased the AUC of loperamide by 1.73-fold and the C_{max} by 1.95-fold *[see Drug Interactions (7.1)]*. Administration of trofinetide 2 hours prior to loperamide increased the AUC of loperamide by 1.22-fold and the C_{max} by 1.44-fold.

In Vitro

Trofinetide is not a substrate of CYP450 enzymes, uridine diphosphate glucuronosyltransferase (UGT), or major drug transporters.

Cytochrome P450 (CYP450) Enzymes:

Trofinetide inhibits CYP3A *[see Drug Interactions (7.1)]*. Trofinetide inhibits CYP1A2, 2B6, 2C8, 2C19, and 2D6, but is not expected to result in clinically significant drug interactions. Trofinetide does not inhibit CYP2C9.

UDP-Glucuronosyltransferase (UGT):

Trofinetide inhibits UGT enzymes, UGT1A9, 2B7, and 2B15.

Transporter Systems:

Trofinetide inhibits P-gp *[see Drug Interactions (7.1)]*, BCRP, and BSEP. Trofinetide inhibits OAT1, OCT2, OATP1B1, OATP1B3, MATE1, and MATE2-K, but is not expected to

result in clinically significant drug interactions. Trofinetide does not inhibit OAT3.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

Studies to evaluate the carcinogenic potential of trofinetide have not been conducted.

Mutagenesis

Trofinetide was negative in in vitro (bacterial reverse mutation, chromosomal aberration in Chinese hamster ovary cells) and in vivo (mouse micronucleus) assays.

Impairment of Fertility

Oral administration of trofinetide (0, 150, 450, or 1000 mg/kg twice daily; 0, 300, 900, or 2000 mg/kg/day) to male and female rats prior to and throughout mating and continuing in females through gestation day 7 resulted in no adverse effects on fertility or reproductive function. Plasma exposures at the highest dose tested were less than that in humans at the maximum recommended human dose of 12,000 mg/dose (24,000 mg/day).

14 CLINICAL STUDIES

DAYBUE STIX

The effectiveness of DAYBUE STIX has been established from an adequate and well-controlled study of DAYBUE for the treatment of Rett syndrome and demonstration of similar pharmacokinetics between DAYBUE STIX for oral solution and DAYBUE oral solution *[see Clinical Pharmacology (12.3)]*. Presented below is a display of the efficacy results of the adequate and well-controlled study of DAYBUE in patients with Rett syndrome.

DAYBUE

The efficacy of DAYBUE for the treatment of Rett syndrome was established in a 12-week randomized, double-blind, placebo-controlled study in patients with Rett syndrome 5 to 20 years of age (Study 1; NCT04181723).

Patients (N=187) had a diagnosis of typical Rett syndrome according to the Rett Syndrome Diagnostic Criteria with a documented disease-causing mutation in the *MECP2* gene. Patients were randomized to receive DAYBUE (N=93) or matching placebo (N=94) for 12 weeks. The DAYBUE dosage was based on patient weight to achieve similar exposure in all patients *[see Dosage and Administration (2.1)]*.

The co-primary efficacy measures were change from baseline after 12 weeks of treatment in the total score of the Rett Syndrome Behaviour Questionnaire (RSBQ) and the Clinical Global Impression-Improvement (CGI-I) score. The RSBQ is a 45-item rating scale completed by the caregiver that assesses a range of symptoms of Rett syndrome (breathing, hand movements or stereotypies, repetitive behaviors, night-time behaviors, vocalizations, facial expressions, eye gaze, and mood). Each item is scored as 0 (not true), 1 (somewhat or sometimes true), or 2 (very true or often true), with a maximum

possible score of 90 points. Lower scores reflect lesser severity in signs and symptoms of Rett syndrome. The CGI-I is rated by clinicians to assess whether a patient has improved or worsened on a 7-point scale (1=very much improved to 7=very much worse) in which a decrease in score indicates improvement.

Treatment with DAYBUE demonstrated a statistically significant difference in favor of DAYBUE as compared to placebo on the co-primary efficacy endpoints, the change from baseline in RSBQ total score, and the CGI-I score at week 12 (**Table 6**, **Figure 1**, and **Figure 2**).

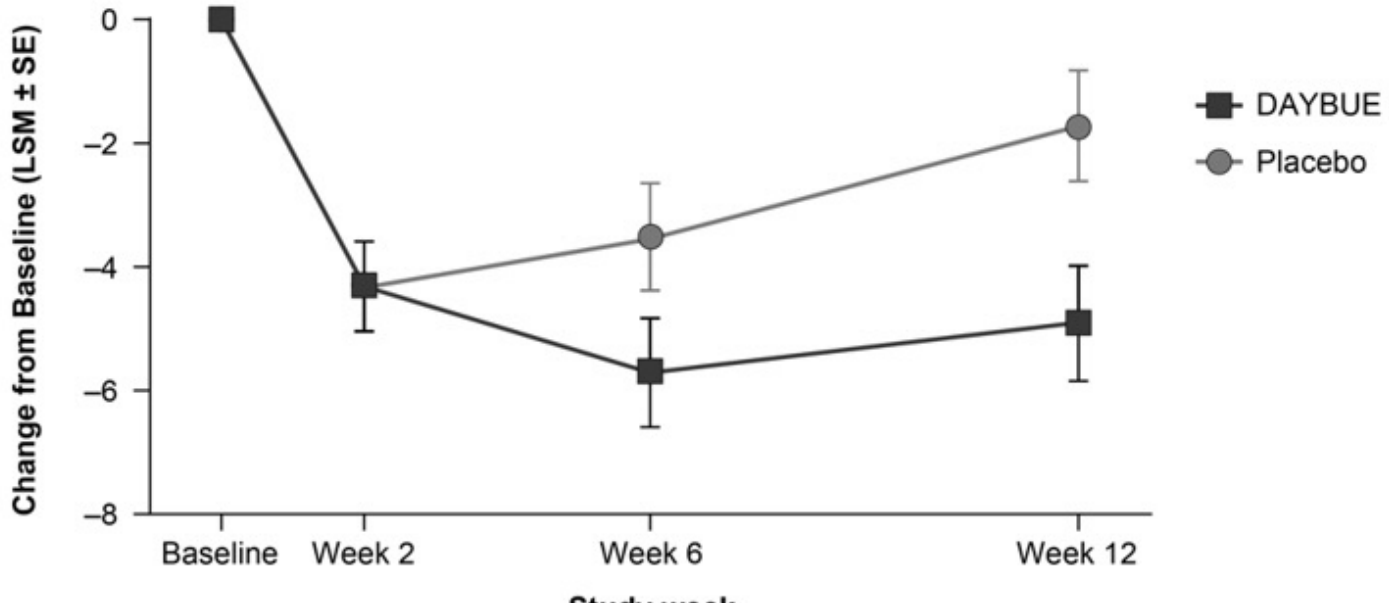
Table 6 Summary of Study 1 Efficacy Results

		Mean Baseline Score (SE)	**Mean Week 12 Score (SE)**	**LS Mean Change from Baseline to Week 12 (SE)**	**DAYBUE-Placebo Treatment Difference, LS Mean (95% CI)***	**p-value**
RSBQ	DAYBUE	43.7 (1.21)	39.9 (1.38)	-4.9 (0.94)	-3.2 (-5.7, -0.6)	0.018
	Placebo	44.5 (1.26)	42.8 (1.42)	-1.7 (0.90)		
CGI-I	DAYBUE	--	3.5 (0.08)	--	-0.3 (-0.5, -0.1)	0.003
	Placebo	--	3.8 (0.06)			

CI=confidence interval; LS mean=least-squares mean; SE=standard error

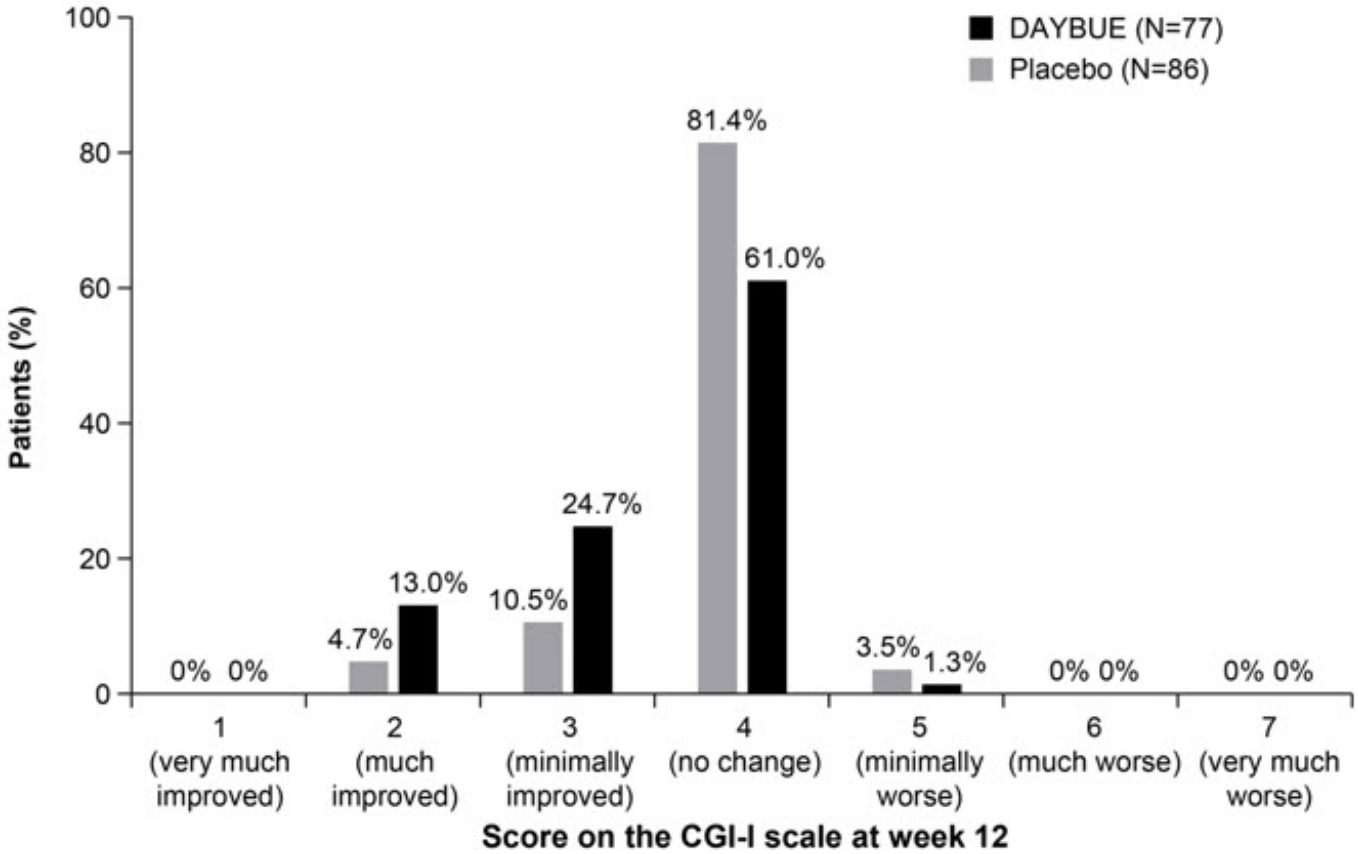
* Difference in LS mean from the mixed-effect model for repeated measure analysis

Figure 1 Change From Baseline in RSBQ Total Score in Study 1



Number of patients				
Placebo	93	90	92	85
DAYBUE	91	90	83	76

Figure 2 Distribution of CGI-I Scores for Patients Completing Study 1



16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

DAYBUE (trofinetide) 200 mg/mL oral solution is a pink to red, strawberry flavored solution supplied in a round high-density polyethylene (HDPE) multi-dose bottle with a child-resistant closure containing 450 mL of oral solution (NDC 63090-660-01).

DAYBUE STIX (trofinetide) for oral solution is a white, off-white to pinkish powder with a strawberry flavor supplied in multi-layer aluminum packets as follows:

	Package Configuration and NDC Number	
Strength	**Individual Packet**	**Carton of 60 Packets**
5,000 mg	63090-663-01	63090-663-60
6,000 mg	63090-664-01	63090-664-60
8,000 mg	63090-665-01	63090-665-60

16.2 Storage and Handling

DAYBUE Oral Solution

Store DAYBUE in an upright position refrigerated at 2°C to 8°C (36°F to 46°F). Do not freeze.

Keep the child-resistant cap tightly closed.

Discard any unused DAYBUE oral solution after 14 days of first opening the bottle.

DAYBUE STIX for Oral Solution

Store DAYBUE STIX packets at 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].

17 PATIENT COUNSELING INFORMATION

Advise the caregiver or patient to read the FDA-approved patient labeling (Patient Information).

Preparation and Administration

Advise the caregiver or patient that DAYBUE or DAYBUE STIX may be given orally or via gastrostomy (G) tube; doses administered via gastrojejunal (GJ) tubes must be administered through the G-port. DAYBUE or DAYBUE STIX may be taken with or without food *[see Dosage and Administration (2.1)].*

Instruct the caregiver or patient to obtain a calibrated measuring device, such as an oral syringe or oral dosing cup, from the pharmacy. A household measuring cup, teaspoon, or tablespoon is not an adequate measuring device *[see Dosage and Administration (2.2, 2.3)]*.

DAYBUE Oral Solution

Instruct the caregiver or patient to discard any unused DAYBUE oral solution after 14 days from first opening the bottle.

DAYBUE STIX for Oral Solution

Advise the caregiver or patient that DAYBUE STIX for oral solution powder must be

dissolved in a cold to room temperature water or water-based beverage (juice, tea, lemonade, limeade, or liquid hydration) prior to administration *[see Dosage and Administration (2.3)]*. Instruct the caregiver or patient on how much water or water-based beverage is needed to dissolve the contents of DAYBUE STIX packet(s).

Instruct the caregiver or patient to administer the prepared oral solution immediately and not to store for future use. Any prepared oral solution not administered must be discarded.

Instruct patients to not attempt to use partial packets to prepare a dose.

Diarrhea

Advise the caregiver or patient that DAYBUE or DAYBUE STIX can cause diarrhea. Instruct the patient to stop taking laxatives before starting DAYBUE or DAYBUE STIX. If diarrhea occurs, patients should notify their healthcare provider, consider starting antidiarrheal treatment, and monitor hydration status and increase oral fluids, if needed *[see Warnings and Precautions (5.1)]*.

Weight Loss

Inform the caregiver or patient that DAYBUE or DAYBUE STIX may cause weight loss and to notify their healthcare provider if weight loss occurs *[see Warnings and Precautions (5.2)]*.

Vomiting

Advise the caregiver or patient that DAYBUE or DAYBUE STIX can cause vomiting and if vomiting occurs after DAYBUE or DAYBUE STIX administration, do not take an additional dose, but continue with the next scheduled dose *[see Dosage and Administration (2.5)]*. Instruct patients to notify their healthcare provider if vomiting does not stop despite medical management *[see Warnings and Precautions (5.3)]*.

Storage

DAYBUE Oral Solution

Keep bottles of DAYBUE upright and refrigerated before and after opening. Do not freeze *[see How Supplied/Storage and Handling (16.2)]*.

Marketed by:
Acadia Pharmaceuticals Inc. San Diego, CA 92130 USA

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PATIENT INFORMATION

DAYBUE® (day-BYOO) (trofinetide) oral solution	**DAYBUE® STIX (day-BYOO STIX) (trofinetide) for oral solution**

What is DAYBUE or DAYBUE STIX?

- DAYBUE or DAYBUE STIX are prescription medicines used to treat Rett syndrome in adults and children 2 years of age and older.

It is not known if DAYBUE or DAYBUE STIX is safe and effective in children under 2

years of age.

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

- have kidney problems.
- are pregnant or plan to become pregnant. It is not known if DAYBUE or DAYBUE STIX will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if DAYBUE or DAYBUE STIX passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby while taking DAYBUE or DAYBUE STIX.

Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking DAYBUE or DAYBUE STIX with certain medicines may affect the way other medicines work and can cause serious side effects.
Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take DAYBUE or DAYBUE STIX?

- Take DAYBUE or DAYBUE STIX exactly as your healthcare provider tells you to take it.
- If you have kidney problems, talk to your healthcare provider about the right dose of DAYBUE or DAYBUE STIX.
- If you take laxatives, stop taking them before starting treatment with DAYBUE or DAYBUE STIX.
- DAYBUE or DAYBUE STIX may be given by mouth or through a gastrostomy (G) tube. If DAYBUE or DAYBUE STIX is given through a gastrojejunal (GJ) tube, the G-port must be used.
- DAYBUE or DAYBUE STIX may be taken with or without food.
- Your pharmacist should provide an oral syringe or dosing cup that is needed to measure your prescribed dose of DAYBUE or the amount of liquid to mix with DAYBUE STIX powder. A household measuring cup, teaspoon, or tablespoon is not an adequate measuring device.
- **If you are taking DAYBUE oral solution**:
  - Throw away any unused DAYBUE oral solution after 14 days of first opening the bottle.
- **If you are taking DAYBUE STIX for oral solution**:
  - Open each packet only when you are ready to use it.
  - DAYBUE STIX powder must be dissolved in cold to room temperature water or water-based beverage (juice, tea, lemonade, or liquid hydration).
  - Your healthcare provider will tell you how much cold to room temperature water or water-based beverage to use to dissolve the powder in each packet.
  - Empty the entire contents of the DAYBUE STIX packets needed for your prescribed dose into the measured liquid. Do not attempt to use part of a packet.
  - Stir until the powder is completely dissolved.
  - After the powder is dissolved, take the prepared oral solution right away. **Do not** store for future use.
  - Throw away any prepared oral solution that was not taken.
- Your healthcare provider may change your dose or stop treatment with DAYBUE or DAYBUE STIX if needed.
- If you vomit after taking a dose of DAYBUE or DAYBUE STIX, **do not take** another dose to make up for that dose. Wait and take the next dose at your usual time. Call

your healthcare provider if your vomiting does not stop.
- If you miss a dose of DAYBUE or DAYBUE STIX, skip that dose and take your next dose at your usual time. **Do not** take 2 doses to make up the missed dose.

What are the possible side effects of DAYBUE or DAYBUE STIX?
DAYBUE or DAYBUE STIX may cause side effects, including:

- **Diarrhea.** Diarrhea is a common side effect of DAYBUE or DAYBUE STIX that can sometimes be severe. Diarrhea may cause you to lose too much water from your body (dehydration). Tell your healthcare provider if you have diarrhea while taking DAYBUE or DAYBUE STIX. Your healthcare provider may ask you to increase the amount you drink or take antidiarrheal medicine as needed.
- **Weight loss.** DAYBUE or DAYBUE STIX can cause weight loss. Tell your healthcare provider if you notice you are losing weight at any time during treatment with DAYBUE or DAYBUE STIX.
- **Vomiting.** Vomiting is a common side effect of DAYBUE or DAYBUE STIX. Sometimes vomit can get into your lungs (aspiration), which could cause an infection (aspiration pneumonia). Tell your healthcare provider if you have severe vomiting or if vomiting happens often.

The most common side effects of DAYBUE or DAYBUE STIX include diarrhea and vomiting.
These are not all the possible side effects of DAYBUE or DAYBUE STIX. Tell your healthcare provider if you have any side effects that bother you or do not go away. For more information, ask your healthcare provider or pharmacist. 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 DAYBUE or DAYBUE STIX?

- **DAYBUE oral solution**:
  - Store DAYBUE oral solution bottle in the refrigerator between 36°F to 46°F (2°C to 8°C). **Do not** freeze.
  - Keep DAYBUE oral solution bottle in an upright position.
  - Keep the child-resistant cap on the bottle tightly closed.
- **DAYBUE STIX for oral solution**:
  - Store DAYBUE STIX for oral solution powder packets at room temperature between 68°F to 77°F (20°C to 25°C).

Keep DAYBUE, DAYBUE STIX, and all medicines out of the reach of children.

General information about the safe and effective use of DAYBUE or DAYBUE STIX.
Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use DAYBUE or DAYBUE STIX for a condition for which it was not prescribed. Do not give DAYBUE or DAYBUE STIX 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 DAYBUE or DAYBUE STIX that is written for health professionals.

What are the ingredients in DAYBUE or DAYBUE STIX?
Active ingredient: trofinetide
DAYBUE oral solution inactive ingredients: FD&C Red No. 40, maltitol, methylparaben sodium, propylparaben sodium, purified water, strawberry flavor, and sucralose.

DAYBUE STIX for oral solution inactive ingredients: natural strawberry flavor and sucralose.

Marketed by Acadia Pharmaceuticals Inc., San Diego, CA 92130 USA

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For more information, go to www.daybue.com or call 1-844-422-2342.

This Patient Information has been approved by the U.S. Food and Drug Administration

Issued: 12/2025

PRINCIPAL DISPLAY PANEL – 450 ML ORAL SOLUTION BOTTLE LABEL

NDC 63090-660-01

450 mL
Rx only

Daybue™
(trofinetide)
oral solution

200 mg/mL

Recommended Dosage:
See prescribing information.

For oral or G-tube administration only.

PRINCIPAL DISPLAY PANEL – 450 ML ORAL SOLUTION BOTTLE CARTON

NDC 63090-660-01

Daybue™
(trofinetide)
oral solution

200 mg/mL

Recommended Dosage:
See prescribing information.

For oral or G-tube administration only.

450 mL

Rx only

PRINCIPAL DISPLAY PANEL – 5,000 MG FOR ORAL SOLUTION POWDER PACKET

NDC 63090-663-01

Daybue® Stix

(trofinetide)
for oral solution

5,000 mg

For Oral or G-tube administration only

Keep out of reach of children

Rx Only

PRINCIPAL DISPLAY PANEL – 5,000 MG FOR ORAL SOLUTION POWDER CARTON

NDC 63090-663-60

Daybue® Stix
(trofinetide)
for oral solution

5,000 mg
per packet

For Oral or G-tube
administration only

60 Packets

Rx Only

NDC 63090-663-60

Daybue® Stix
(trofinetide)
for oral solution

5,000 mg
per packet

For Oral or G-tube administration only

60 Packets
Rx Only

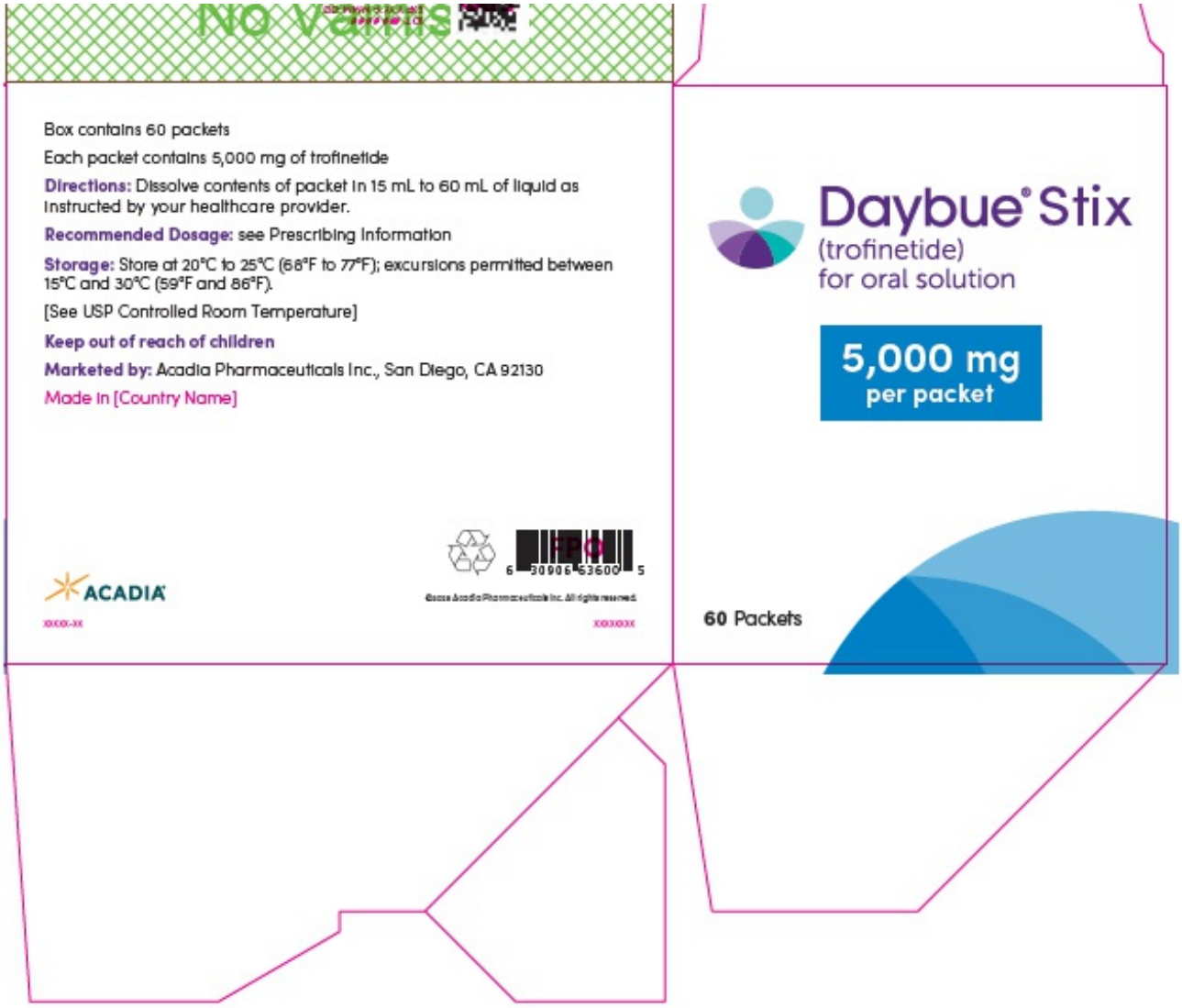
Daybue® Stix
(trofinetide)
for oral solution

5,000 mg
per packet

60 Packets

5,000 mg
per packet

Daybue® Stix
(trofinetide)
for oral solution



PRINCIPAL DISPLAY PANEL – 6,000 MG FOR ORAL SOLUTION POWDER PACKET

NDC 63090-664-01

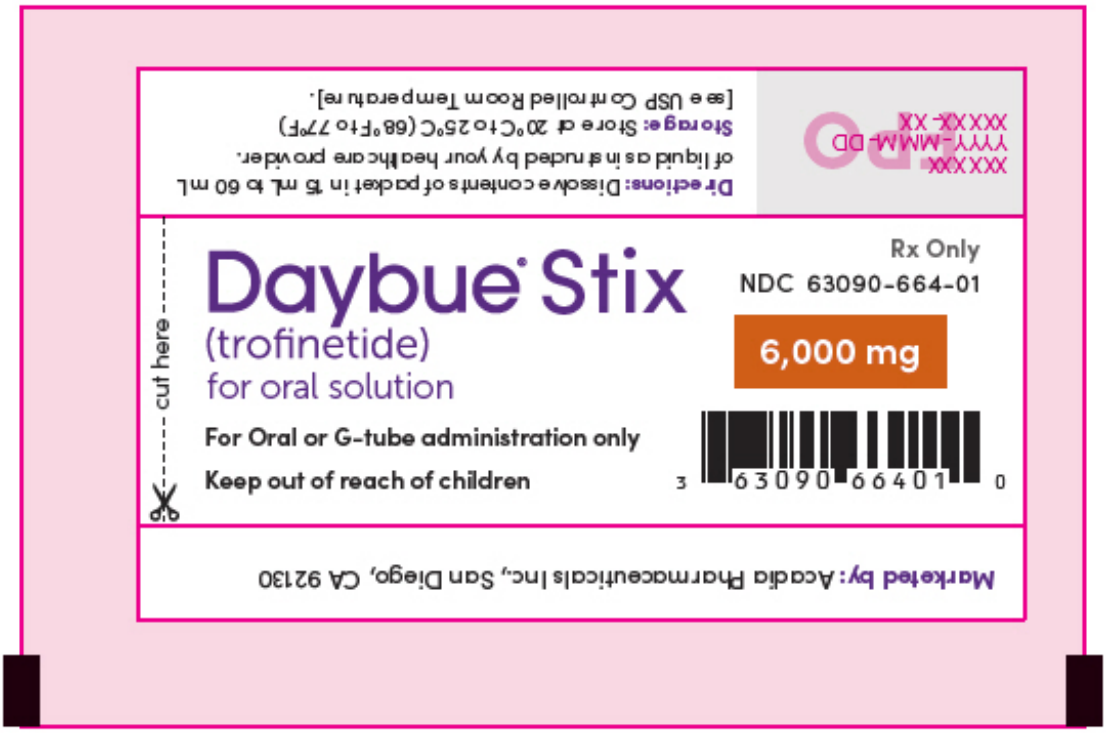
Daybue® Stix
(trofinetide)
for oral solution

6,000 mg

For Oral or G-tube administration only

Keep out of reach of children

Rx Only



PRINCIPAL DISPLAY PANEL – 6,000 MG FOR ORAL SOLUTION POWDER CARTON

NDC 63090-664-60

Daybue® Stix
(trofinetide)
for oral solution

6,000 mg
per packet

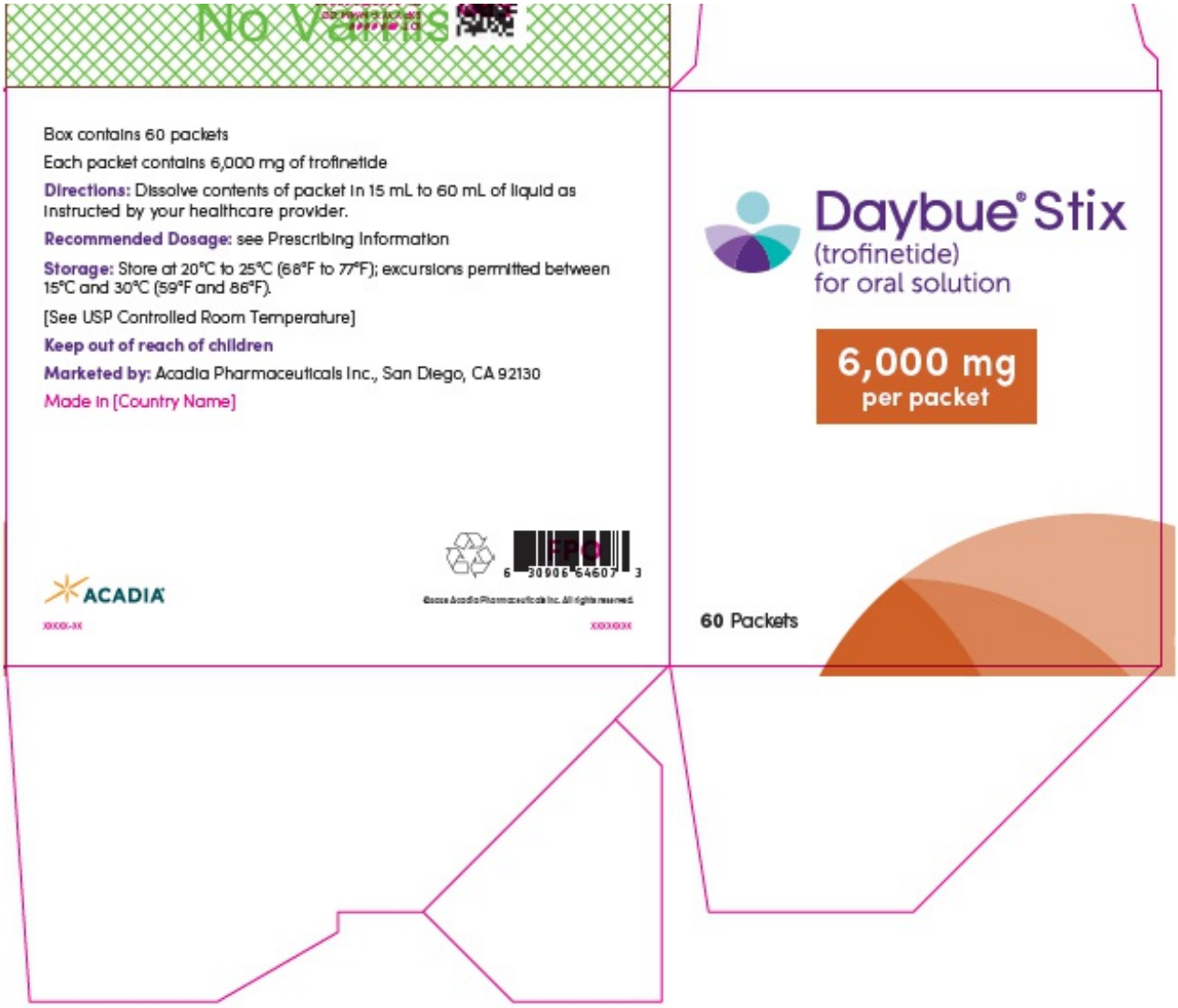
For Oral or G-tube
administration only

60 Packets

Rx Only

NDC 63090-664-60
Daybue® Stix
(trofinetide)
for oral solution
6,000 mg
per packet
For Oral or G-tube
administration only
60 Packets
Rx Only
Daybue® Stix
(trofinetide)
for oral solution
6,000 mg
per packet
60 Packets

6,000 mg
per packet
Daybue® Stix
(trofinetide)
for oral solution



PRINCIPAL DISPLAY PANEL – 8,000 MG FOR ORAL SOLUTION POWDER PACKET

NDC 63090-665-01

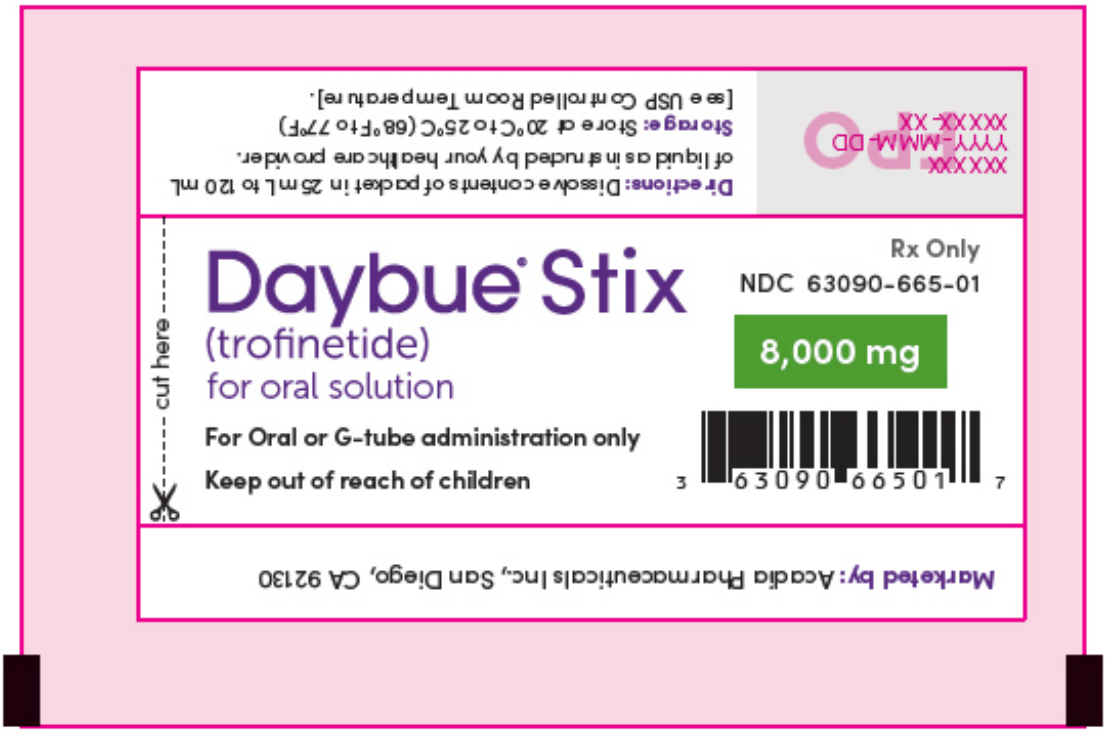
Daybue® Stix
(trofinetide)
for oral solution

8,000 mg

For Oral or G-tube administration only

Keep out of reach of children

Rx Only



PRINCIPAL DISPLAY PANEL – 8,000 MG FOR ORAL SOLUTION POWDER CARTON

NDC 63090-665-60

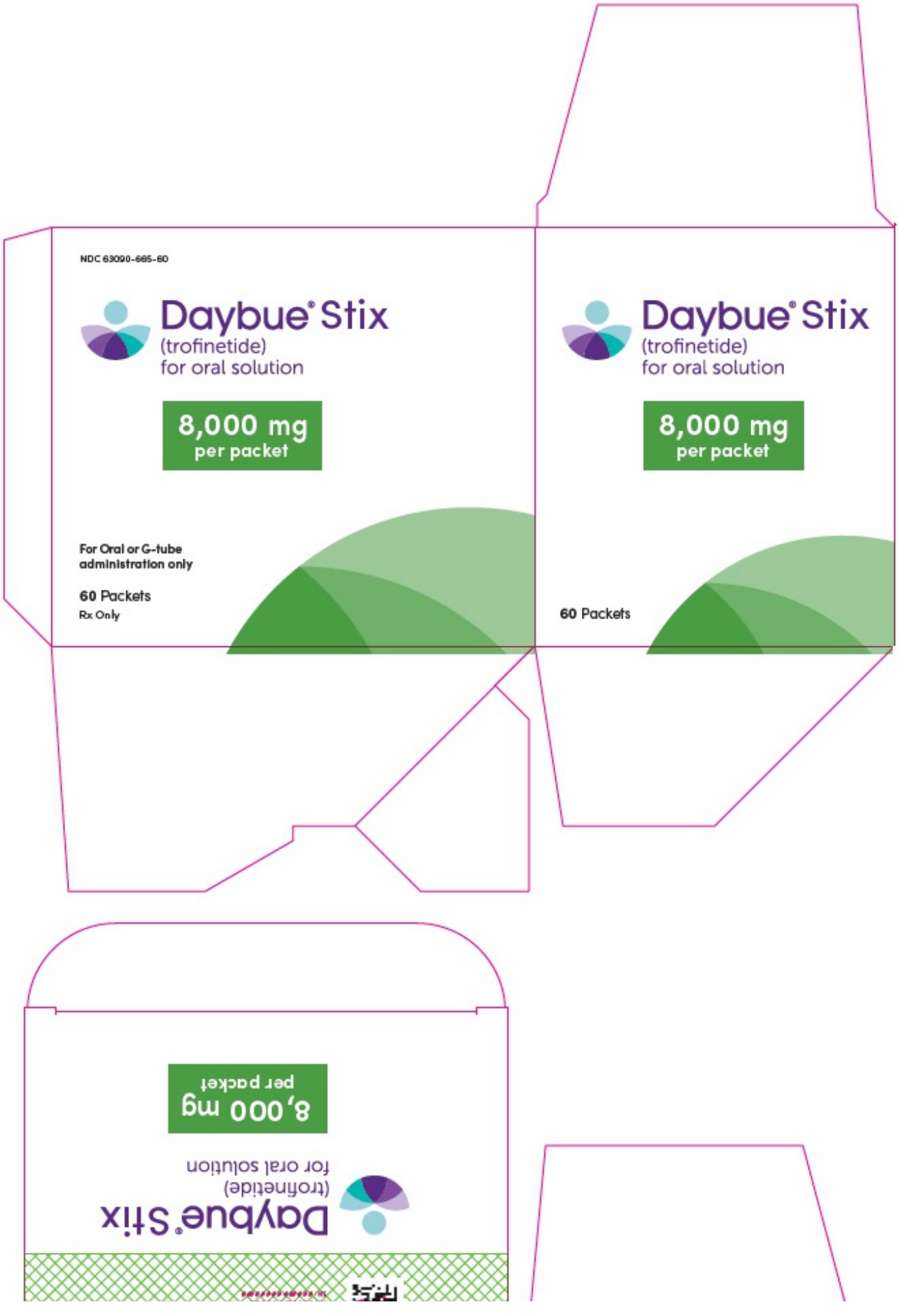
Daybue® Stix
(trofinetide)
for oral solution

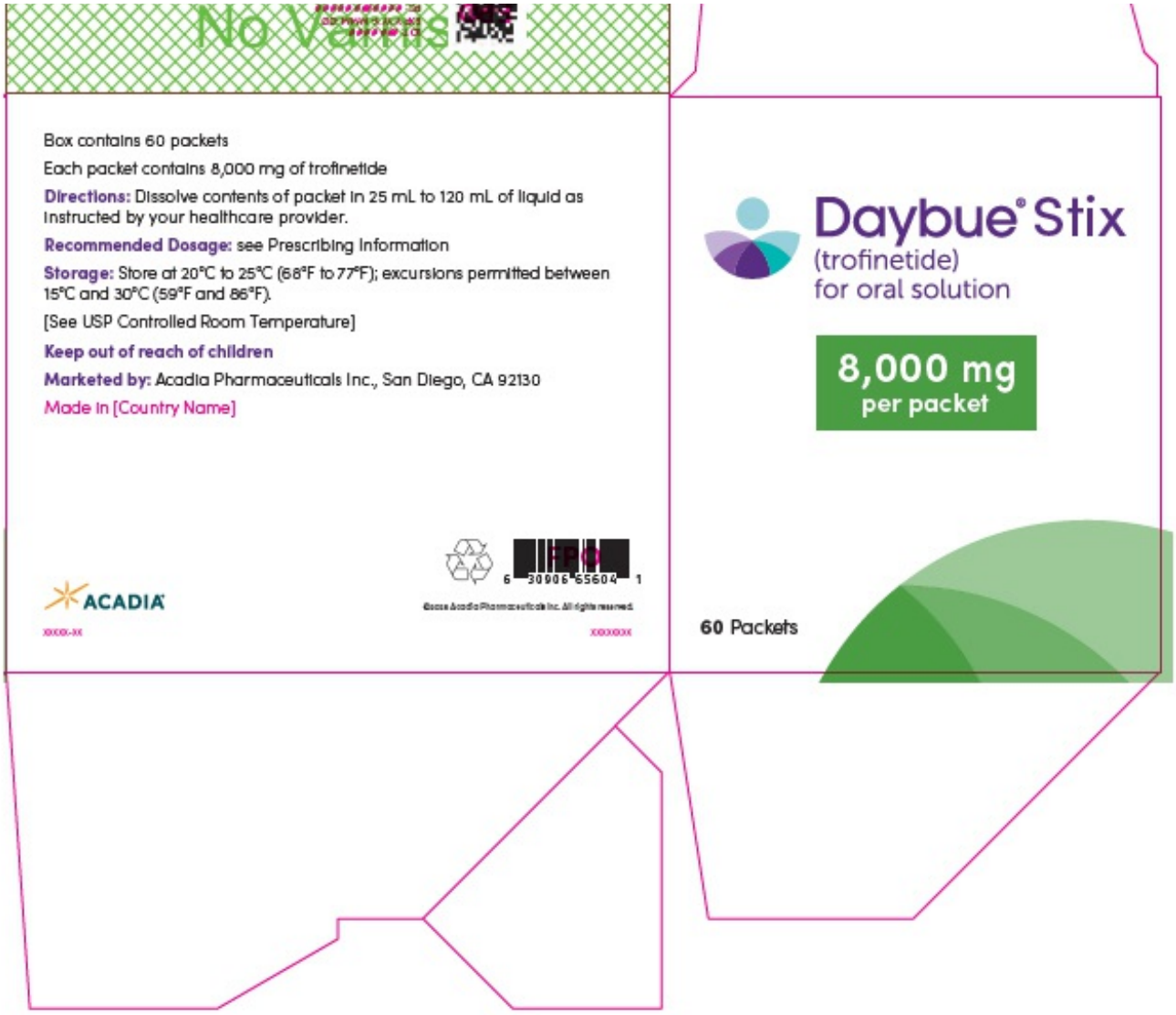
8,000 mg
per packet

For Oral or G-tube
administration only

60 Packets

Rx Only


NDC 63090-665-60
Daybue® Stix
(trofinetide)
for oral solution
8,000 mg
per packet
For Oral or G-tube
administration only
60 Packets
Rx Only
Daybue® Stix
(trofinetide)
for oral solution
8,000 mg
per packet
60 Packets
8,000 mg
per packet
Daybue® Stix
(trofinetide)
for oral solution



DAYBUE

trofinetide solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:63090-660
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
trofinetide (UNII: Z2ME8F52QL) (trofinetide - UNII:Z2ME8F52QL)	trofinetide	200 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
maltitol (UNII: D65DG142WK)	
methylparaben sodium (UNII: CR6K9C2NHK)	

propylparaben sodium (UNII: 625NNB0G9N)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
sucralose (UNII: 96K6UQ3ZD4)	
water (UNII: 059QF0KO0R)	

Product Characteristics			
Color	PINK (Pink to red)	**Score**	
Shape		**Size**	
Flavor	STRAWBERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63090-660-01	1 in 1 CARTON	03/10/2023	
1		450 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA217026	03/10/2023	

DAYBUE STIX

trofinetide for solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:63090-663
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
trofinetide (UNII: Z2ME8F52QL) (trofinetide - UNII:Z2ME8F52QL)	trofinetide	5000 mg

Inactive Ingredients

Ingredient Name	Strength
sucralose (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color	PINK (white, off-white to pinkish)	**Score**	
Shape		**Size**	
Flavor	STRAWBERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63090-663-60	60 in 1 CARTON	12/11/2025	
1	NDC:63090-663-01	1 in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA219884	12/11/2025	

DAYBUE STIX

trofinetide for solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:63090-664
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
trofinetide (UNII: Z2ME8F52QL) (trofinetide - UNII:Z2ME8F52QL)	trofinetide	6000 mg

Inactive Ingredients

Ingredient Name	Strength
sucralose (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color	PINK (white, off-white to pinkish)	**Score**	
Shape		**Size**	
Flavor	STRAWBERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63090-664-60	60 in 1 CARTON	12/11/2025	
1	NDC:63090-664-01	1 in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA219884	12/11/2025	

DAYBUE STIX

trofinetide for solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:63090-665
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
trofinetide (UNII: Z2ME8F52QL) (trofinetide - UNII:Z2ME8F52QL)	trofinetide	8000 mg

Inactive Ingredients

Ingredient Name	Strength
sucralose (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color	PINK (white, off-white to pinkish)	**Score**	
Shape		**Size**	
Flavor	STRAWBERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63090-665-60	60 in 1 CARTON	12/11/2025	
1	NDC:63090-665-01	1 in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA219884	12/11/2025	

Labeler - Acadia Pharmaceuticals Inc. (963571302)

Revised: 9/2026 Acadia Pharmaceuticals Inc.