Coding and Product Fact Sheet for DAYBUE® and DAYBUE® STIX

acadia connect | Daybue® (trofinetide) oral solution | Daybue® Stix (trofinetide) for oral solution

	DAYBUE	DAYBUE STIX		
Indication[1]	Treatment of Rett syndrome in adults and pediatric patients 2 years of age and older			
Dosage & Administration[1]	• Recommended dosing is twice daily, morning and evening, according to patient weight (see dosing chart on back page) • Can be taken with or without food • Can be given orally or via gastrostomy (G) tube • Doses administered via gastrojejunal (GJ) tubes must be administered through the G-port • See the accompanying full Prescribing Information for complete dosing information, including dose modifications			
	N/A	Prior to administration, DAYBUE STIX must be dissolved in a cold to room temperature water or water-based beverage (juice, tea, lemonade, limeade, or liquid hydration)		
Contraindications[1]	None			
Description and Package Size[1]	Pink to red, strawberry flavored solution supplied in a round HDPE multi-dose bottle with a child-resistant closure containing 450 mL of oral solution	White, off-white to pinkish powder with a strawberry flavor supplied in multi-layer aluminum packets		
Storage and Handling[1]	• Store 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	• Store 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)		
Product Image				
Dosage Strength[1]	**200 mg/mL**	**5,000 mg**	**6,000 mg**	**8,000 mg**
11-digit NDC[1,*]	63090-**0**660-01	63090-**0**663-60	63090-**0**664-60	63090-**0**665-60
Diagnosis Code (ICD-10-CM)[2]	F84.2 (Rett syndrome)			
Syringes for Administration[3]	One of the following 3 syringes will be provided (depending on route of administration): • NeoMed® Oral Dispenser • ENFit® • Luer Lock Syringe			
Ordering & Distribution	• Ordered through the DAYBUE and DAYBUE STIX Prescription and Enrollment Form • Distributed exclusively through AnovoRx Specialty Pharmacy			

C=Celsius; F=Fahrenheit; HDPE=high-density polyethylene; ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification; NDC=National Drug Code.

*NDCs have been "zero-filled" in bold to create an 11-digit code that meets general billing standards.

IMPORTANT SAFETY INFORMATION

- **Warnings and Precautions**
  - **Diarrhea:** In a 12-week study 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 mild or moderate in 96% of cases. In the 12-week study, 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 additional Important Safety Information on the following page. Please read the accompanying full Prescribing Information, also available at DAYBUEhcp.com.

Preparation and Administration Information[1]

		DAYBUE Oral Solution	DAYBUE STIX		
Patient Weight	DAYBUE Dosage	Volume	Packet Number and Strength	Volume Needed to Dissolve Dose†	Administered Volume
9 kg to <12 kg	5,000 mg twice daily	25 mL twice daily	**One 5,000 mg packet**	15 mL to 60 mL	Administer solution twice daily
12 kg to <20 kg	6,000 mg twice daily	30 mL twice daily	**One 6,000 mg packet**		
20 kg to <35 kg	8,000 mg twice daily	40 mL twice daily	**One 8,000 mg packet**	25 mL to 120 mL	
35 kg to <50 kg	10,000 mg twice daily	50 mL twice daily	**Two 5,000 mg packets**	30 mL to 120 mL (each packet requires 15 mL to 60 mL)	
≥50 kg	12,000 mg twice daily	60 mL twice daily	**Two 6,000 mg packets**		

†Volume should be selected within the recommended range based on individual patient factors.[1]

See the accompanying full Prescribing Information for complete dosing information, including dose modifications.

IMPORTANT SAFETY INFORMATION (cont'd)

- **Warnings and Precautions (cont'd)**
  - **Vomiting:** In a 12-week study, vomiting occurred in 29% of patients treated with DAYBUE and in 12% of patients who received placebo.

    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.
  - **Weight Loss:** In the 12-week study, 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.
- **Adverse Reactions:** The common adverse reactions (≥5% for DAYBUE-treated patients and at least 2% greater than in placebo) reported in the 12-week study were diarrhea (82% vs 20%), vomiting (29% vs 12%), fever (9% vs 4%), seizure (9% vs 6%), anxiety (8% vs 1%), decreased appetite (8% vs 2%), fatigue (8% vs 2%), and nasopharyngitis (5% vs 1%).
- **Drug Interactions: Effect of DAYBUE and DAYBUE STIX on other Drugs**
  - Trofinetide, a weak inhibitor of CYP3A and an inhibitor of P-gp, can increase the plasma concentrations of CYP3A and/or P-gp substrates (e.g., loperamide), which may increase the risk of adverse reactions associated with these substrates.

    Closely monitor patients when DAYBUE or DAYBUE STIX is administered concomitantly with sensitive CYP3A and/or P-gp substrates for which a minimal increase in substrate plasma concentration (i.e., drugs with a narrow therapeutic index) may lead to serious adverse reactions.
- **Use in Specific Population: Renal Impairment**
  - DAYBUE and DAYBUE STIX are not recommended for patients with severe renal impairment.

DAYBUE is available as an oral solution (200 mg/mL).
DAYBUE STIX for oral solution powder is available in 5,000 mg, 6,000 mg, and 8,000 mg packets.

Please read the accompanying full Prescribing Information, also available at DAYBUEhcp.com.

For more information, please visit DAYBUEhcp.com

Call Acadia Connect at 1-844-737-2223, Monday to Friday, 8AM to 8PM ET, to learn more about our personalized support program, designed to help meet the needs of your patients taking DAYBUE

Please note that this content is for informational purposes only and does not constitute medical, legal, or reimbursement advice, and represents no statement, promise, or guarantee of coverage or payment. Healthcare providers are solely responsible for determining appropriate treatment for their patients. Individual health insurance policies are frequently updated, and it is the responsibility of the provider to determine and submit appropriate coding, medical necessity, site of service, and documentation, as specified by the patient's health insurance.

References: 1. Acadia Pharmaceuticals Inc. DAYBUE [package insert]. San Diego, CA; 2025. **2.** Centers for Medicare & Medicaid Services. ICD-10-CM tabular list of diseases and injuries. Updated August 7, 2025. Accessed October 14, 2025. https://www.cms.gov/medicare/coding-billing/icd-10-codes. **3.** Data on file. Acadia Pharmaceuticals Inc. San Diego, CA.

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