Coding and Product Fact Sheet for DAYBUE™ (trofinetide)

acadia connect® | Daybue™ (trofinetide)

This document is an overview of product and coding information that may be helpful when prescribing DAYBUE and seeking coverage for your patients.

Indication[1]

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

Dosage and Administration[1]

- The recommended dosing for DAYBUE is twice daily, morning and evening, according to patient weight, as shown in the table on the right. It can be taken with or without food.
- DAYBUE can be given orally or via gastrostomy (G) tube. Doses administered via gastrojejunal (GJ) tubes must be administered through the G-port.
- See the full Prescribing Information for complete dosing information, including dose modifications.

Recommended Dose[1]

Patient Weight	DAYBUE Dose
9 kg to <12 kg	25 mL twice daily
≥12 kg to <20 kg	30 mL twice daily
≥20 kg to <35 kg	40 mL twice daily
≥35 kg to <50 kg	50 mL twice daily
≥50 kg	60 mL twice daily

How Supplied

- DAYBUE is a pink to red, strawberry flavored solution supplied in a nominal 500 mL round high-density polyethylene (HDPE) multi-dose bottle containing 450 mL of oral solution[1]
- Each 5 mL contains 1 g of trofinetide (200 mg/mL)[1]
- Healthcare providers can choose between a NeoMed® Oral Dispenser, ENFit®, or Luer Lock Syringe to be dispensed with DAYBUE

National Drug Code (NDC)[1]		Diagnosis Code (ICD-10-CM)[2]	
10-digit NDC	63090-660-01	Rett syndrome	F84.2
11-digit NDC	63090-0660-01		

ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification.

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. 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 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.

For more information, please visit DAYBUE.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.

IMPORTANT SAFETY INFORMATION (cont'd)

- **Warnings and Precautions: 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 if vomiting is severe or occurs despite medical management.
- **Warnings and Precautions: 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 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 on other Drugs**
  - DAYBUE is a weak CYP3A4 inhibitor; therefore, plasma concentrations of CYP3A4 substrates may be increased if given concomitantly with DAYBUE. Closely monitor when DAYBUE is used in combination with orally administered CYP3A4 sensitive substrates for which a small change in substrate plasma concentration may lead to serious toxicities.
  - Plasma concentrations of OATP1B1 and OATP1B3 substrates may be increased if given concomitantly with DAYBUE. Avoid the concomitant use of DAYBUE with OATP1B1 and OATP1B3 substrates for which a small change in substrate plasma concentration may lead to serious toxicities.
- **Use in Specific Population: Renal Impairment**
  - DAYBUE is not recommended for patients with severe renal impairment.

DAYBUE is available as an oral solution (200mg/mL).

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

References: 1. Acadia Pharmaceuticals Inc. DAYBUE [package insert]. San Diego, CA; 2024. **2.** Centers for Medicare & Medicaid Services. ICD-10-CM tabular list of diseases and injuries. Updated September 26, 2024. Accessed October 3, 2024. https://www.cms.gov/medicare/coding-billing/icd-10-codes.

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