

Daily Treatment Journal

Tracking your child's journey with DAYBUE™ oral solution

Before and after beginning your child's treatment with DAYBUE, this Daily Treatment Journal provides a handy resource you may want to use to track your child's treatment journey over the next several months. Consider sharing it with your child's care team, which may help inform your child's care.



Indication and Important Safety Information

What is DAYBUE?

DAYBUE is a prescription medicine used to treat Rett syndrome in adults and children 2 years of age and older. It is not known if DAYBUE is safe and effective in children under 2 years of age.

What are the possible side effects of DAYBUE?

- Diarrhea: Diarrhea is a common side effect of DAYBUE that can sometimes be severe. Diarrhea may cause you to lose too much water from your body (dehydration). Before starting treatment with DAYBUE, stop taking laxatives. Tell your healthcare provider if you have diarrhea while taking DAYBUE. Your healthcare provider may ask you to increase the amount you drink or take antidiarrheal medicine as needed.
- Weight loss: DAYBUE can cause weight loss. Tell your healthcare provider if you notice you are losing weight at any time during treatment with DAYBUE.
- The most common side effects of DAYBUE were diarrhea and vomiting. Other side effects include fever, seizure, anxiety, decreased appetite, tiredness, and the common cold. These are not all the possible side effects of DAYBUE. Tell your healthcare provider if you have any side effects that bother you or do not go away.

What should I tell my healthcare provider before taking DAYBUE?

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

Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking DAYBUE with certain medicines may affect how the other medicines work and can cause serious side effects.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088. You can also call Acadia Pharmaceuticals Inc. at 1-844-4ACADIA (1-844-422-2342).

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

The risk information provided here is not comprehensive.

To learn more, talk with your healthcare provider and read the full <u>Prescribing Information</u>, including <u>Patient Information</u>, also available at <u>DAYBUE.com</u>



Start here: 7 days before beginning treatment with DAYBUE



Consider tracking your child's bowel movements for the next 7 days

One week before starting treatment with DAYBUE, consider tracking your child's bowel movements on the following pages using the Bristol Stool Chart as a guide. This will help you establish a "bowel movement baseline." If your child tends to be constipated or often has loose stools, tracking this information will help to inform your doctor of your child's bowel habits before treatment with DAYBUE begins.

Compare your child's stool to the examples on the Bristol Stool Chart and consider using the 7-Day Stool Tracker on the next page to log each day.

Bristol Stool Chart

The Bristol Stool Chart is used to assess the texture and shape of bowel movements. While it's not required to assess diarrhea in your child, it may be a useful tool when comparing your child's stool.

Type 1	Separate hard lumps,like nuts (hard to pass)
Type 2	Sausage-shaped but lumpy
Type 3	Like a sausage but with cracks on the surface
Type 4	Like a sausage or snake, smooth and soft
Type 5	Soft blobs with clear-cut edges
Type 6	Fluffy pieces with ragged edges, a mushy stool
Type 7	Watery, no solid pieces. Entirely liquid

Adapted from: Harvey S, Matthai S, King DA. How to use the Bristol Stool Chart in childhood constipation. *Arch Dis Child Educ Pract Ed.* 2022;edpract-2022-324513.



7-Day Stool Tracker

Date/Time	Box Move Yes	wel ment No	Medications/Supplements for Diarrhea/Constipation Given	Describe Stool Type/condition/color



At the end of 7 days and before beginning treatment with DAYBUE, show your completed 7-Day Stool Tracker to your doctor.

Current medications and/or supplements for constipation or diarrhea may be adjusted by your doctor before your child's treatment with DAYBUE begins.

Beginning treatment with DAYBUE

This is a hopeful and exciting time for you and your family as you begin your child's treatment with DAYBUE. Tracking your child's treatment journey will help you and your doctor recognize changes. This may also help you track how certain symptoms and behaviors of Rett syndrome may change over time.

After 12 weeks of the clinical trial, some caregivers saw improvements in the signs and symptoms of Rett syndrome. But because results are variable and can change over time, this journal has several months' worth of pages.



Track your child's treatment journey and share it with your Rett care team

This journal is in an easy-to-use format where you can jot down notes about your child's journey on DAYBUE.

acadia connect

Support by your side



Acadia Connect® is a patient and family support program that connects you and your family with educational support and resources throughout the DAYBUE treatment journey.

The team will help you with:

- Understanding and verifying insurance coverage
- Information on appropriate financial assistance options
- Support and education throughout the DAYBUE treatment journey

For more information about treatment with DAYBUE, or to reorder a Daily Treatment Journal, please call Acadia Connect at 1-844-737-2223, Monday–Friday, 8:00 AM to 8:00 PM ET.

Congratulations. Your child's treatment journey with DAYBUE has begun.



Daily notes	Date:	Daily notes	Date:
Morning Dose Amount Given:	Evening Dose Amount Given:	Morning Dose Amount Given:	Evening Dose Amount Given:
Weight:		Weight:	



Daily notes	Date:	Daily notes	Date:
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- It is not known if DAYBUE is safe and effective in children under 2 years of age.

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

Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Taking DAYBUE 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?

- Take DAYBUE exactly as your healthcare provider tells you to take it.
- If you take laxatives, stop taking them before starting treatment with DAYBUE.
- Your healthcare provider may change your dose or stop treatment with DAYBUE if needed.
- Your pharmacist should provide an oral syringe or dosing cup that is needed to measure your prescribed dose. Do
 not use a household measuring cup.
- DAYBUE may be taken by mouth or given through a gastrostomy (G) tube. If DAYBUE is given through a
 gastrojejunal (GJ) tube, the G-port must be used.
- DAYBUE may be taken with or without food.
- Throw away any unused DAYBUE after 14 days of first opening the bottle.
- If you vomit after taking a dose of DAYBUE, **do not take** another dose to make up for that dose. Wait and take the next dose at your usual time.
- If you miss a dose of DAYBUE, 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?

DAYBUE may cause side effects, including:

- **Diarrhea.** Diarrhea is a common side effect of DAYBUE 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. Your healthcare provider may ask you to increase the amount you drink or take antidiarrheal medicine as needed.
- **Weight loss.** DAYBUE can cause weight loss. Tell your healthcare provider if you notice you are losing weight at any time during treatment with DAYBUE.

The most common side effects of DAYBUE include diarrhea and vomiting.

These are not all the possible side effects of DAYBUE. 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?

- Store DAYBUE in the refrigerator between 36°F to 46°F (2°C to 8°C). **Do not** freeze.
- Keep DAYBUE in an upright position.
- Keep the child-resistant cap tightly closed.

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

General information about the safe and effective use of DAYBUE.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use DAYBUE for a condition for which it was not prescribed. Do not give DAYBUE 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 that is written for health professionals.

What are the ingredients in DAYBUE?

Active ingredient: trofinetide

Inactive ingredients: FD&C Red No. 40, maltitol, methylparaben sodium, propylparaben sodium, purified water, 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

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