



My Care Guide

Find useful details about me, my caregiver, Rett syndrome, and DAYBUE®

Name:

Age:

Fun facts about me:

My caregiver's contact information:

Indication

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.

Important Safety Information

What are the possible side effects of DAYBUE?

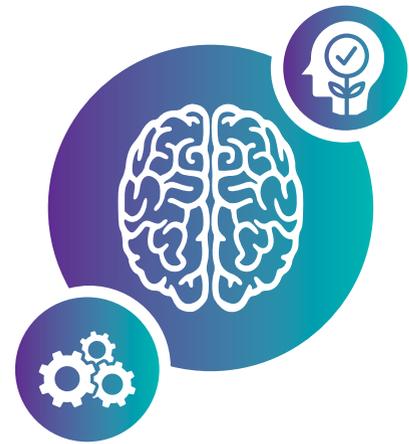
- **Diarrhea:** Diarrhea is a common side effect of DAYBUE that can sometimes be severe. Diarrhea may cause you to lose too much water from your body (dehydration). Before starting treatment with DAYBUE, stop taking laxatives. Tell your healthcare provider if you have diarrhea while taking DAYBUE. Your healthcare provider may ask you to increase the amount you drink or take antidiarrheal medicine as needed.

See additional Important Safety Information throughout. Please read the full [Prescribing Information](#), including [Patient Information](#).

Get to know Rett syndrome

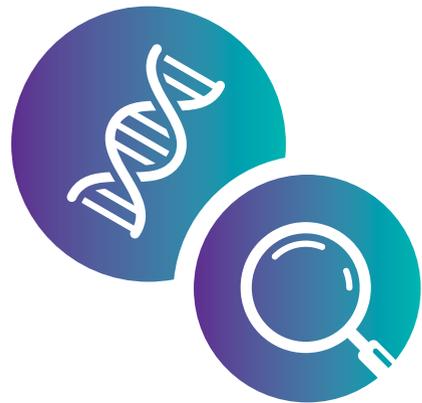
A rare condition that impacts about

6000 to 9000 people in the United States



Rett syndrome is a rare neurodevelopmental condition, meaning it affects how the brain functions and develops.

It is not neurodegenerative, meaning brain cells will not become damaged or die.



Rett syndrome is most common in girls, but it can affect boys too.

Rett syndrome is unique to each person living with it. The symptoms can affect each individual in different ways, at different times, and at different stages of the disorder.

Typical signs and symptoms for a Rett syndrome diagnosis



Partial or complete loss of ability to verbally communicate



Trouble walking or loss of ability to walk



Repetitive hand movements like washing, balled up hands, hands in mouth, clapping, or pulling hair



Partial or complete loss of ability to use hands for daily activities

Additional challenges associated with Rett syndrome include irregular breathing patterns, epileptic seizures, movement disorders, behavioral disturbances, gastrointestinal disorders, heart issues, curvature of the spine, hip displacement, and bone fractures.

Communication and Rett syndrome

Many individuals with Rett syndrome are cognitively aware but are unable to effectively act on their desire to verbally communicate. They may have trouble using words, making sounds, or controlling hand movements. This can leave them feeling frustrated and misunderstood.

Due to these challenges, their abilities are often underestimated. However, with support from their care team, adaptive tools and communication strategies provide new ways to express themselves.

What you should know about DAYBUE

DAYBUE is the first and only FDA-approved treatment for Rett syndrome in adults and children 2 years of age and older



DAYBUE can help spark meaningful improvements in the signs and symptoms of Rett syndrome

In a clinical trial, DAYBUE was shown to significantly reduce the severity in signs and symptoms of Rett syndrome at 12 weeks as measured by the Rett Syndrome Behaviour Questionnaire (RSBQ) when compared to placebo.

The RSBQ assessed the following signs and symptoms:



Breathing



Hand movements or stereotypies



Repetitive behaviors



Nighttime behaviors



Vocalizations



Facial expressions



Eye gaze



Mood

At 12 weeks, doctors also observed:

Significant improvements in the signs and symptoms of Rett syndrome in patients taking DAYBUE vs placebo.

The CGI-I (Clinical Global Impression-Improvement) scale was used by doctors to evaluate improvement or worsening of Rett symptoms.

- 38% of patients (n=77) had improvement in symptoms with DAYBUE vs 15% of patients (n=86) on placebo

Important note: Because everyone with Rett syndrome is unique—with a unique set of symptoms—the response to DAYBUE may be different for each individual. Not all patients in the clinical trial responded to treatment with DAYBUE.

Help track my progress

You are a valued member of my care team. If you notice any changes in my signs and symptoms of Rett syndrome, please write them down and let my caregiver know. Even small details can provide my doctor with helpful insights.

Use the space below to track any changes you've noticed
(Teeth grinding less, hands are more fluid and open, mood is better, etc)

Important Safety Information (continued)

What are the possible side effects of DAYBUE? (continued)

- **Vomiting:** Vomiting is a common side effect of DAYBUE. 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.

See additional Important Safety Information throughout. Please read the full [Prescribing Information](#), including [Patient Information](#).



Things I may experience

I may have some side effects while at school. The most common of them are diarrhea and vomiting, which are unintentional and not contagious.

I may feel embarrassed, so please help me take care of this private matter quickly and discreetly. Not every person will have the same experience as me. To learn more about managing side effects, read below.



Helpful tips to consider for managing diarrhea

- ✓ Tell the school nurse right away and notify my caregiver if I have diarrhea
- ✓ Keep an eye on my fluid intake, watch for signs of dehydration, and increase my oral fluids if needed. My doctor may have also suggested a fiber supplement—ask my caregiver about it
- ✓ It is recommended that I have antidiarrheal medications such as loperamide (IMODIUM®) at school to help me manage my diarrhea. Please ask my caregiver about the plan we set up with my doctor



Helpful tips to consider for managing vomiting

- ✓ It helps me to have meals somewhere calm. My stomach can be sensitive to stress, so finding somewhere relaxed to eat can reduce the likelihood of vomiting. If I start vomiting, please help me sit forward to prevent choking and don't give me an additional dose of DAYBUE
- ✓ It's helpful to avoid meals before nap time

Notes

Want to know more about Rett syndrome and DAYBUE?

Click [HERE](#) to check out other resources to help you better understand me and my condition.

Important Safety Information (continued)

What are the possible side effects of DAYBUE? (continued)

- **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.

See additional Important Safety Information throughout. Please read the full [Prescribing Information](#), including [Patient Information](#).

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.
- **Vomiting:** Vomiting is a common side effect of DAYBUE. 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.
- **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 (200 mg/mL).

The risk information provided here is not comprehensive. To learn more, talk with your healthcare provider and read the full [Prescribing Information](#), including [Patient Information](#), also available at DAYBUE.com.



PATIENT INFORMATION
DAYBUE™ (day-BYOO)
(trofinetide)
oral solution

What is DAYBUE?

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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. Call your healthcare provider if your vomiting does not stop.
- 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.
- **Vomiting.** Vomiting is a common side effect of DAYBUE. 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 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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