



An introduction to DAYBUE™

We're adding more of her sparkle to the world around us

DAYBUE is the first and only FDA-approved treatment for Rett syndrome

Kate, age 9, living with Rett syndrome, with her parents

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 on page 21. Please read the full [Prescribing Information](#), including [Patient Information](#).





An opportunity to help spark meaningful improvements in the signs and symptoms of Rett syndrome


For the loved one you've always known is inside, DAYBUE is the first and only FDA-approved prescription medicine for the treatment of Rett syndrome in adults and children 2 years of age and older.

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 on page 21.

A photograph of a young girl with long brown hair, wearing a light blue cardigan over a white shirt, smiling broadly while sitting at a table. She is eating a meal. To her right, the side profile of a woman with long dark hair, wearing a white cardigan over an orange top, is visible. The scene is set in a brightly lit dining area. A glowing, golden circular halo surrounds the girl's head.

Kate, age 9, living with Rett syndrome, with her mom

Rett syndrome: A complex genetic disorder with a range of symptoms—but limited treatment options



Rett syndrome is a rare neurodevelopmental disorder that can cause lifelong complications. **Your child's experience with Rett syndrome is unique to them**—the symptoms can affect every individual in different ways, at different times, and at different stages of the disorder.



As varied as these symptoms can be, your child can also experience unexpected setbacks called regressions. **This may leave you and your family continually seeking new solutions to the ongoing changes in your child.**



Along with a variation in symptoms, the ability to think and understand may also vary among children. Many children with Rett syndrome are cognitively aware but are unable to effectively act on their desire to communicate. This may leave them feeling frustrated and misunderstood.

In Rett syndrome,
a majority of cases
are caused
by a mutation,
or change,
in the *MECP2* gene.



MECP2 is thought to control how many genes work, including those important for brain development.



In Rett syndrome, mutations in *MECP2* are thought to disrupt the activity of these genes which may be associated with symptoms of Rett syndrome.

How was DAYBUE studied?

The effectiveness and safety of DAYBUE were evaluated in the 12-week LAVENDER™ clinical trial of 187 females aged 5 to 20 with Rett syndrome



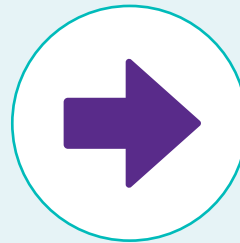
12-week clinical trial



187 patients

LAVENDER

During the trial, 93 patients were given DAYBUE, and their results were compared with those of 94 patients who were given a placebo (treatment without any active medication).



Up to 40-week study



154 patients

LILAC™

Following the 12-week LAVENDER clinical trial, eligible patients and their families were given the option to continue treatment with DAYBUE (or start treatment with DAYBUE if they had previously received a placebo).

Patients in LAVENDER all had a diagnosis of typical Rett syndrome according to the Rett Syndrome Diagnostic Criteria, and a documented mutation in the *MECP2* gene. And, to reflect how unique Rett syndrome is for each person, patients in both groups of the study had a range of symptoms and disease severity.

Because caregivers possess such a deep knowledge of their child, they contributed directly to the evaluation of the overall effectiveness of DAYBUE. Doctors evaluated if patients improved or got worse, while caregivers looked for changes in the signs and symptoms of Rett syndrome.



Kate, age 9, living with Rett syndrome (right), with her sister and dad

Caregivers evaluated changes in a range of symptoms using the Rett Syndrome Behaviour Questionnaire (RSBQ)

What does the RSBQ measure?

An instrument used in studies of Rett syndrome, the RSBQ is a measurement scale used by caregivers to evaluate 45 items representing symptoms of Rett syndrome. Caregivers were asked to rate each item as it relates to their child. These are examples of the types of symptoms that caregivers evaluated. Each item is scored as 0 (not true), 1 (somewhat or sometimes true), or 2 (very true or often true), with a maximum score of 90 points.



Breathing



Hand movements
or stereotypies



Repetitive behaviors



Nighttime behaviors



Vocalizations



Facial expressions



Eye gaze



Mood

What improvements could DAYBUE help spark?

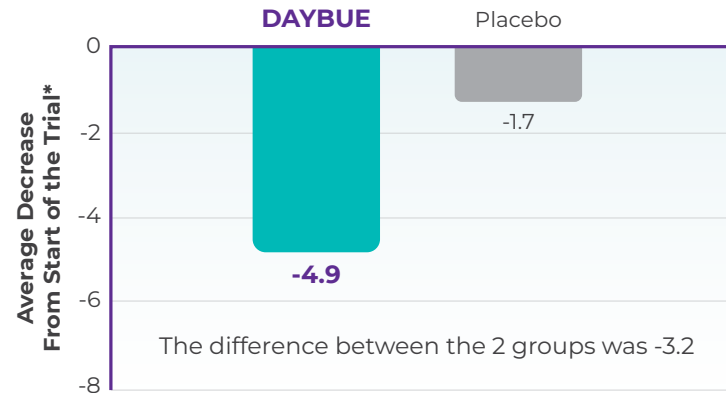
After caregivers completed the RSBQ, the scores of the 45 items were added up to determine the **RSBQ total score**. The maximum possible score was 90.

To determine how symptoms were impacted by treatment, researchers looked at how much the average RSBQ total score changed for all patients in the clinical trial at 12 weeks of treatment.

Help illuminate more of the girl you've always known was inside with DAYBUE

At 12 weeks, caregivers observed:

Change in average RSBQ total score from the start of the trial to Week 12



The patients receiving DAYBUE saw **almost 3x greater decrease in average RSBQ total score** from the start of the trial when compared with placebo. **A lower score meant signs and symptoms of Rett syndrome were less severe.**

In this evaluation, there were 76 patients in the DAYBUE group and 85 in the placebo group.

Before starting treatment, the average RSBQ total score for the DAYBUE group was 43.7. For the placebo group, the average RSBQ total score before treatment was 44.5.

*Results varied between patients in the clinical trial. Individual results may vary with DAYBUE.

Important Safety Information (continued)

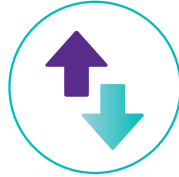
What are the possible side effects of DAYBUE? (continued)

- **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.

See additional Important Safety Information on page 21.



Doctors evaluated improvement or worsening of Rett syndrome using the Clinical Global Impression-Improvement (CGI-I) scale



Improvement or worsening in individuals were evaluated starting from before treatment began through the 12-week trial.

They did this using a 7-point scale, from 1, which meant “very much improved,” to 7, which meant “very much worse.”



Results: At 12 weeks, **doctors saw a global improvement** in Rett syndrome signs and symptoms in patients receiving DAYBUE when compared to patients receiving the placebo.

Because each individual with Rett syndrome is unique—with a unique set of symptoms—improvements in the signs and symptoms of Rett syndrome with DAYBUE may be different for everyone.

At 12 weeks, doctors observed:

Improvement was seen by doctors in nearly **4 out of 10 patients (38%)** taking DAYBUE at 12 weeks, compared with less than 2 out of 10 (15%) of those taking the placebo.

	1	2	3	4	5	6	7
	Very much improved ↑	Much improved ↑	Minimally improved ↑	No change	↓ Minimally worse	↓ Much worse	↓ Very much worse
DAYBUE	0%	13%	24.7%	61%	1.3%	0%	0%
Placebo	0%	4.7%	10.5%	81.4%	3.5%	0%	0%

In this evaluation, there were 77 patients in the DAYBUE group and 86 in the placebo group.

Individual results may vary with DAYBUE.

Important Safety Information (continued)

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.

See additional Important Safety Information on page 21.

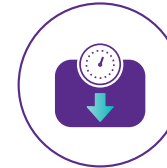


Understanding the possible side effects of DAYBUE

As with any medication, it's important to talk to your child's doctor about the possibility of side effects with DAYBUE. Not every person will experience the same side effects, and for some people, certain side effects, such as diarrhea and vomiting, may be more severe than others. **Side effects may include:**



Diarrhea: Diarrhea is a common side effect of DAYBUE that can sometimes be severe. Diarrhea may cause your child to lose too much water from their body (dehydration). Tell your doctor if your child has diarrhea while taking DAYBUE. Your doctor may ask you to increase the amount your child drinks or give antidiarrheal medicine as needed.



Weight loss: DAYBUE can cause weight loss. Tell your doctor if you notice your child is losing weight at any time during treatment with DAYBUE.

Common side effects experienced during the 12-week LAVENDER trial are listed on the next page.

Common side effects in the 12-week LAVENDER trial

Side Effects	DAYBUE (% of 93 patients)	Placebo (% of 94 patients)
Diarrhea	82%	20%
Vomiting	29%	12%
Fever	9%	4%
Seizure	9%	6%
Anxiety	8%	1%
Decreased appetite	8%	2%
Tiredness	8%	2%
Common cold	5%	1%

See page 15 for helpful tips for managing diarrhea.

Information about diarrhea from the DAYBUE clinical studies:

- More than 8 out of 10 patients (85%) treated with DAYBUE experienced diarrhea
- In those treated with DAYBUE, almost 5 out of 10 patients (49%) had diarrhea that would not go away, or that came back after it had stopped, even when pausing DAYBUE treatment, reducing the amount of DAYBUE given, or using antidiarrheal medicine
- Diarrhea was mild or moderate in more than 9 out of 10 cases (96%)
- None of the patients in the clinical studies had to go to the hospital because of diarrhea

In LAVENDER (the 12-week trial):

- 5 out of 10 patients (51%) treated with DAYBUE used antidiarrheal medication
- Patients experienced diarrhea regardless of a previous history of constipation



Kate's story with DAYBUE



*Kate, age 9, living
with Rett syndrome,
with her parents*

For many parents, a diagnosis of Rett syndrome can be bittersweet. For Jen and Jim, they finally had an answer as to what was causing their 3-year-old daughter Kate's sudden repetitive hand behaviors, speech regressions, and missing motor milestones. But having that answer also brought up the many challenges, impacts, and unknowns of life with a rare disease. As her caregivers, they knew the journey might not be easy for them. More than anything, they wanted something that might make it easier for Kate.

There were no approved treatments for her condition. Kate worked with an occupational therapist to develop and strengthen her hand functions, as well as a speech therapist and physical therapist. She was not taking any other daily medications to manage her symptoms. Jen and Jim felt excited and hopeful when Kate entered the clinical trials with DAYBUE at age 7.

Important Safety Information (continued)

What should I tell my healthcare provider before taking DAYBUE? (continued)

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.

See additional Important Safety Information on page 21.



As part of the clinical trials, Jen and Jim saw improvements in Kate. One of the noticeable changes was more purposeful hand use. Kate is able to point at and touch her tablet and even use a spoon. Her mood has improved; she seems more peaceful at home, at school, and in larger groups. She's also better able to use her eye-gaze device to talk to her family. Jen and Jim saw improvements with how she uses her eyes and her hands to communicate using her TOBII device—making it easier for them to understand her.

Shortly after starting DAYBUE, Kate started having diarrhea. While it doesn't happen every day, when it does occur, it can require multiple diaper changes and can happen multiple times a day. This was a different experience for her family, as Kate struggled with constipation before the trial and

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See additional Important Safety Information on page 21.



sometimes had to take laxatives. When the diarrhea first started, Kate's parents worked with their healthcare team to come up with strategies for managing the diarrhea. In consultation with her healthcare team, Kate's parents stopped giving her laxatives and instead started an antidiarrheal every day, which has helped make her bowel movements more solid.

Jen and Jim continue to be hopeful for what the next steps in Kate's journey may bring.

Important Note: Kate was a DAYBUE clinical trial patient. She continues to take DAYBUE and is enrolled in Acadia Connect®. The experiences of Kate and her family may not be the same as yours. Because each individual with Rett syndrome is unique—with a unique set of symptoms—the response to DAYBUE may be different for everyone. See pages 8 through 13 for the clinical trial results. Always speak with a healthcare provider about your own experience. Kate's family was compensated for participating in a photo shoot and sharing their story.

Kate, age 9, living with Rett syndrome (center), with her brothers



Helpful tips for managing diarrhea



If you are accustomed to treating for constipation, managing diarrhea may be new to you. Diarrhea did occur in some individuals taking DAYBUE who previously experienced constipation. Before your child starts treatment, talk to your doctor about a management plan to address the possible reactions of diarrhea while on treatment with DAYBUE.

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 on page 21.

Before your child starts treatment with DAYBUE:

- ✓ Consider keeping a log to track stool consistency/frequency for one week before starting treatment
- ✓ Tell your doctor if you are giving your child stool softeners and other medicines or dietary supplements for the treatment of constipation
- ✓ Stop use of laxatives
- ✓ Talk to your doctor about any recommended dietary changes including potential use of supplemental fiber

Acadia Connect is here to support you throughout the DAYBUE treatment journey.
For more information, see page 20.



If diarrhea occurs:

- ✔ Tell your doctor if your child has diarrhea
- ✔ Keep an eye on your child's fluid intake and watch for signs of dehydration; increase oral fluids, if needed. Your doctor may also suggest a fiber supplement, if appropriate
- ✔ It is recommended that you have antidiarrheal medications such as loperamide (IMODIUM®) at home so you can manage diarrhea as needed
- ✔ Your doctor may reduce the dose of DAYBUE or may ask you to stop giving your child DAYBUE until the diarrhea improves. Do not stop giving DAYBUE before talking to your doctor

Important Safety Information (continued)

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

- **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.

See additional Important Safety Information on page 21.

Considering DAYBUE? Talk to your doctor to see if DAYBUE may be right for your child

Important Safety Information (continued)

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.

See additional Important Safety Information on page 21.



Kate, age 9, living with Rett syndrome

A few facts when considering treatment with DAYBUE



DAYBUE is an oral medication that should be taken **twice daily**, morning and evening



If your child **vomits** after taking a dose of DAYBUE, do not give them another dose to make up for that dose. Wait and give them the next dose at their usual time



DAYBUE is a **strawberry flavored** liquid formula that can be swallowed or given through a gastrostomy (G) tube



If your child **misses a dose** of DAYBUE, skip that dose and give the next dose at their usual time. Do not give two doses to make up the missed dose



DAYBUE can be taken **with or without food**



If your child has a **gastrojejunal (GJ) tube**, DAYBUE must be given through the G-port

Important Safety Information (continued)

What should I tell my healthcare provider before taking DAYBUE? (continued)

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.

See additional Important Safety Information on page 21.

A few facts when considering treatment with DAYBUE (continued)



DAYBUE should be **stored upright in the refrigerator** before and after opening



DAYBUE will be **shipped directly to your home** via a specialty pharmacy



Discard any unused DAYBUE after 14 days of opening the bottle



Dedicated support for DAYBUE is available through Acadia Connect

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 on page 21.



Kate, age 9, living with Rett syndrome

Support by your side

Once your child is prescribed DAYBUE, you'll have the team at Acadia Connect to help guide you through the treatment journey. Acadia Connect is a patient and family support program that connects you and your family with educational support and resources.

*Kristine,
Family Access
Manager*



Acadia Connect team members are ready to help

acadia
connect®

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

Acadia Connect consists of a dedicated, experienced support team:

Nurse Care Coordinator who welcomes you to Acadia Connect and provides ongoing support throughout the DAYBUE treatment journey

Family Access Manager who helps you understand your insurance coverage, provides information about DAYBUE, and delivers education about potential side effects, tools, and resources for you and your child who is prescribed DAYBUE

Visit AcadiaConnect.com or call 1-844-737-2223, Monday–Friday, 8:00AM to 8:00PM ET to learn more about how Acadia Connect can provide you and your child with support throughout the DAYBUE treatment journey.

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What are the possible side effects of DAYBUE?

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- **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 accompanying [Patient Information](#). Visit DAYBUE.com for the full [Prescribing Information](#).



See what meaningful improvements DAYBUE may help spark in your child



Proven effective

By 12 weeks, treatment with DAYBUE demonstrated improvements in signs and symptoms of Rett syndrome, as measured by both caregivers and doctors



Twice-daily dosing

DAYBUE is a strawberry flavored oral medication taken twice a day by mouth or G/GJ tube



Common side effects

Diarrhea and vomiting are the most common side effects with DAYBUE. Your doctor can provide tips and strategies to help



Dedicated patient support

Once your child is prescribed DAYBUE, Acadia Connect is here to provide you with dedicated support and resources throughout the treatment journey



Talk to your doctor about FDA-approved DAYBUE.

Visit [DAYBUE.com](https://www.daybue.com) to learn more.

*Kate, age 9, living with **Rett syndrome**, with her brother*

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 on page 21. Please read the full [Prescribing Information](#), including [Patient Information](#).



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

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.

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 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

Approved 3/2023