

PATIENT INFORMATION

DAYBUE® (day-BYOO)
(trofinetide)
oral solution

DAYBUE® STIX (day-BYOO STIX)
(trofinetide)
for oral solution

What is DAYBUE or DAYBUE STIX?

- DAYBUE or DAYBUE STIX are prescription medicines used to treat Rett syndrome in adults and children 2 years of age and older.

It is not known if DAYBUE or DAYBUE STIX is safe and effective in children under 2 years of age.

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

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

Taking DAYBUE or DAYBUE STIX 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 or DAYBUE STIX?

- Take DAYBUE or DAYBUE STIX exactly as your healthcare provider tells you to take it.
- If you have kidney problems, talk to your healthcare provider about the right dose of DAYBUE or DAYBUE STIX.
- If you take laxatives, stop taking them before starting treatment with DAYBUE or DAYBUE STIX.
- DAYBUE or DAYBUE STIX may be given by mouth or through a gastrostomy (G) tube. If DAYBUE or DAYBUE STIX is given through a gastrojejunal (GJ) tube, the G-port must be used.
- DAYBUE or DAYBUE STIX may be taken with or without food.
- Your pharmacist should provide an oral syringe or dosing cup that is needed to measure your prescribed dose of DAYBUE or the amount of liquid to mix with DAYBUE STIX powder. A household measuring cup, teaspoon, or tablespoon is not an adequate measuring device.
- **If you are taking DAYBUE oral solution:**
 - Throw away any unused DAYBUE oral solution after 14 days of first opening the bottle.
- **If you are taking DAYBUE STIX for oral solution:**
 - Open each packet only when you are ready to use it.
 - DAYBUE STIX powder must be dissolved in cold to room temperature water or water-based beverage (juice, tea, lemonade, or liquid hydration).
 - Your healthcare provider will tell you how much cold to room temperature water or water-based beverage to use to dissolve the powder in each packet.
 - Empty the entire contents of the DAYBUE STIX packets needed for your prescribed dose into the measured liquid. Do not attempt to use part of a packet.
 - Stir until the powder is completely dissolved.
 - After the powder is dissolved, take the prepared oral solution right away. **Do not** store for future use.
 - Throw away any prepared oral solution that was not taken.
- Your healthcare provider may change your dose or stop treatment with DAYBUE or DAYBUE STIX if needed.
- If you vomit after taking a dose of DAYBUE or DAYBUE STIX, **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 or DAYBUE STIX, 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 or DAYBUE STIX?

DAYBUE or DAYBUE STIX may cause side effects, including:

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

- **Vomiting.** Vomiting is a common side effect of DAYBUE or DAYBUE STIX. 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 or DAYBUE STIX include diarrhea and vomiting.

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

- **DAYBUE oral solution:**
 - Store DAYBUE oral solution bottle in the refrigerator between 36°F to 46°F (2°C to 8°C). **Do not freeze.**
 - Keep DAYBUE oral solution bottle in an upright position.
 - Keep the child-resistant cap on the bottle tightly closed.
- **DAYBUE STIX for oral solution:**
 - Store DAYBUE STIX for oral solution powder packets at room temperature between 68°F to 77°F (20°C to 25°C).

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

General information about the safe and effective use of DAYBUE or DAYBUE STIX.

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

What are the ingredients in DAYBUE or DAYBUE STIX?

Active ingredient: trofinetide

DAYBUE oral solution inactive ingredients: FD&C Red No. 40, maltitol, methylparaben sodium, propylparaben sodium, purified water, strawberry flavor, and sucralose.

DAYBUE STIX for oral solution inactive ingredients: natural strawberry flavor and sucralose.

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For more information, go to www.daybue.com or call 1-844-422-2342.