

Acadia Pharmaceuticals Inc. is providing this letter in response to your unsolicited request for medical information. It is for scientific exchange and individual educational purposes only, and should not be copied or distributed. Information included in this letter may not be consistent with the US FDA-approved Prescribing Information for DAYBUE® (trofinetide) or may be related to unapproved uses of DAYBUE. This letter is not intended to advocate any unapproved or approved use, indication, dosage, or other treatment-related decision. Acadia strives to provide current, accurate, and fair-balanced information in compliance with current industry information dissemination guidelines.

For further information regarding Indication and Important Safety Information for DAYBUE, please click here: <u>Prescribing Information</u>.



DAYBUE® (trofinetide) Carbohydrate Content

This letter is provided in response to your specific request for information regarding carbohydrates in DAYBUE.

DAYBUE (trofinetide) Oral Solution 200 mg/mL contains 30 mg/mL maltitol.¹ Carbohydrate content and percentage of daily carbohydrate intake for recommended doses of DAYBUE by patient weight, based on a ketogenic diet, are shown in **Table 1**.

Table 1. Carbohydrate Content and Percentage of Daily Carbohydrate Intake for

Recommended Doses of DAYBUE Based on Ketogenic Diet¹⁻³
Carbohydrate

Patient Weight	DAYBUE Volume per Dose	Carbohydrate Content (0.03 g/mL)	Percentage of Daily Carbohydrate Intake Based on Ketogenic Diet*
9 kg to less than 12 kg	25 mL twice daily	1.5 grams daily	7.5–12.5%
12 kg to less than 20 kg	30 mL twice daily	1.8 grams daily	9–15%
20 kg to less than 35 kg	40 mL twice daily	2.4 grams daily	12–20%
35 kg to less than 50 kg	50 mL twice daily	3.0 grams daily	15–25%
50 kg or more	60 mL twice daily	3.6 grams daily	18–30%

^{*}Based on ketogenic diet with daily carbohydrate intake between 12 and 20 g per day.3

There are no dietary restrictions associated with DAYBUE use. A list of ingredients is provided in the package insert. If needed, please consult with a dietitian regarding the effect of ingredients in DAYBUE Oral Solution on the diet.

References

- 1. Acadia Pharmaceuticals Inc. Data on File. DAYBUE® (trofinetide) Oral Solution Carbohydrate Content. March 22, 2023.
- 2. DAYBUE® (trofinetide) [package insert]. San Diego, CA. Acadia Pharmaceuticals Inc. [Link]
- 3. McArtney R, Bailey A, Champion H. What is a ketogenic diet and how does it affect the use of medicines? *Arch Dis Child Educ Pract Ed.* 2017;102(4):194-199. [PubMed]