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



## **DAYBUE®** (trofinetide) Taste Management

This letter is being provided based on your specific request for information on managing the taste of DAYBUE.

DAYBUE is a sweetened, strawberry-flavored solution.<sup>1</sup> There is currently no information on the impact on palatability of combining DAYBUE with food or drink.

## Mixing DAYBUE with Lemon or Lime Juice

In a chemical stability study, the addition of 1.65 mL of lemon or lime juice to 10 mL of DAYBUE oral solution (200 mg/mL) was found to have no impact on the chemical stability of the drug product at room temperature for up to 3 hours.<sup>2</sup> This ratio of up to 1:6 (1 part lemon or lime juice, or less, to 6 parts of DAYBUE oral solution) equates to approximately 5 mL or less of lemon or lime juice per each 30 mL measured dose of DAYBUE. A lower quantity of juice may be used if that is sufficient for adjusting taste. ReaLemon<sup>®</sup> and ReaLime<sup>®</sup> were the juices assessed in the stability study.

The impact on palatability of combining DAYBUE with lemon or lime juice has not been assessed. If adding lemon or lime juice to DAYBUE, the juice should only be added to a single dose prior to dosing, and not pre-mixed ahead of time. Juice should not be mixed with the entire bottle of DAYBUE.

## **General Tips for Managing Medication Taste**

The taste of medications may be unpleasant, and some patients may be reluctant to take the medication. **Table 1** includes some general tips for consideration.

#### Table 1. General Tips for Managing Medication Taste\*

#### Before administration of DAYBUE

• Give your child or patient something cold to numb the taste buds before giving them their medication, e.g., ice cream, an ice cube, or ice-cold water.<sup>3</sup>

#### **During administration of DAYBUE**

- Measure the amount of medicine accurately first and then use a medication syringe and gently administer the liquid medication into the side of the cheek. Do not squirt the medication into the back of the throat as this could cause choking.<sup>4</sup>
- When using a syringe, dip the tip in syrup<sup>†</sup> immediately prior to giving the medication.<sup>3</sup>
- If suitable for your child or patient, use play to increase their involvement in taking the medication. For example, pretending to give some medicine to a favorite toy.<sup>3</sup>
- Music therapy improves mood and social interaction in children with Rett syndrome and reduces parent and caregiver stress.<sup>5</sup> Playing a favorite piece of music may help to provide a calm environment while giving medication to your child or patient.

After administration of DAYBUE

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• Give a strong-tasting food or drink after the medication to remove the taste of the medicine.<sup>3</sup>
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#### General tips

• Consider giving the medicine before giving positive rewards.<sup>4</sup>

# Maintain a positive approach when giving medication to your child or patient.<sup>6</sup> This can help make the whole process less stressful as staying calm and positive can affect the child or patient's response to the medication.

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\*This guidance was developed by Acadia Pharmaceuticals Inc. †DAYBUE should not be mixed directly with syrup.

## References

- 1. DAYBUE<sup>™</sup> (trofinetide) [package insert]. San Diego, CA. Acadia Pharmaceutical Inc. [Link]
- 2. Acadia Pharmaceuticals Inc. Data on File. Report 400-00. 2023.
- Bergene EH, Rø TB, Steinsbekk A. Strategies parents use to give children oral medicine: a qualitative study of online discussion forums. *Scand J Prim Health Care*. 2017;35(2):221-228. [PubMed]
- 4. Seattle Children's Hospital. Medicine Refusal to Take. [Link].
- 5. Chou MY, Chang NW, Chen C, et al. The effectiveness of music therapy for individuals with Rett syndrome and their families. *J Formos Med Assoc.* 2019;118(12):1633-1643.
- 6. Great Ormond Street Hospital for Children. Giving your child medicines. [Link].