Fintepla®
(fenfluramine)
2.2 mg/mL oral solution

For seizures associated with **Dravet syndrome** in patients 2 years of age and older

Haidyn, living life with Dravet syndrome, and his mother

Let in more life with fewer seizures

DISCUSSION GUIDE

FINTEPLA for Dravet syndrome

Start a conversation with your loved one's healthcare provider

Indication

- FINTEPLA is indicated for the treatment of seizures associated with Dravet syndrome and Lennox-Gastaut syndrome in patients 2 years of age and older.
- It is not known if FINTEPLA is safe and effective in children less than 2 years of age.

Select Important Safety Information

FINTEPLA can cause serious side effects, including:

Problems with the valves in the heart (valvular heart disease) and high blood pressure in the arteries of the lungs (pulmonary arterial hypertension) have been associated with fenfluramine, the active ingredient in FINTEPLA. Your healthcare provider will do a test called an echocardiogram to check your heart and to evaluate for high blood pressure in the arteries of the lungs before you start taking FINTEPLA, again every 6 months during treatment, and one time 3 to 6 months after you take your last dose of FINTEPLA.

Please see full Important Safety Information on pages 5-7 and full Prescribing Information, including Medication Guide, at Fintepla.com.

Questions for you to answer ahead of time

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When considering options for better seizure management for your loved one with Dravet syndrome, asking the right questions can help you stay on top of the latest treatment options.

Use this guide to talk to your healthcare provider about how FINTEPLA may make a difference for your loved one. You can also talk to a FINTEPLA Clinical Nurse Educator, who can provide live, individualized support and address your questions about FINTEPLA.

Ask a FINTEPLA Clinical Nurse Educator

FINTEPLA Clinical Nurse Educators are registered nurses who are highly knowledgeable about FINTEPLA and Dravet syndrome.* They can help you prepare for a conversation with your healthcare provider so you can make informed decisions about treatment with FINTEPLA. To speak with a Clinical Nurse Educator, call 1-833-GO-DS-LGS (1-833-463-7547), Monday through Friday, 7:30 AM to 4:30 PM Central Time. Learn more at https://www.fintepla.com/ONWARD-support/.

*The Clinical Nurse Educator cannot provide medical advice or make treatment recommendations and can only provide information about FINTEPLA. Decisions regarding your health and the treatment of your condition should be made with your healthcare provider.

These are the medicines my loved one is currently taking for seizures associated with Dravet syndrome:

My goals for my loved one's seizure treatment plan are:

How well are my loved one's seizures controlled with the current treatment plan?

What challenges are currently keeping us from reaching our treatment goals?

Am I satisfied with my loved one's current treatment plan for Dravet syndrome? ❑ Yes ❑ No

Based on my loved one's current progress, how could additional seizure reduction be beneficial?

How can FINTEPLA help us reach our seizure treatment goals?

Questions for you to ask about FINTEPLA

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Will FINTEPLA work with my loved one's current treatment plan?

Can you tell me more about echocardiograms (echo tests) and why they are needed for treatment with FINTEPLA?

Should I schedule my loved one's echocardiogram at the same time as their doctor appointment?

Is there a facility close to our home where my loved one can get an echocardiogram?

Is there anything I should do to prepare my loved one for the echocardiogram?

How and when would my loved one take FINTEPLA?

What should I watch for after starting my loved one on FINTEPLA? What are the potential risks and benefits of FINTEPLA?

Is there anything else I need to know about FINTEPLA?

Scan QR code.

Watch these educational videos and discuss FINTEPLA with your healthcare provider.

Please see full Important Safety Information on pages 5-7 and full Prescribing Information, including Medication Guide, at Fintepla.com.

Getting started on FINTEPLA

There are a few steps you can take to help your loved one get started on FINTEPLA—even before an appointment with their healthcare provider.

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Step 1:

Fill out the patient sections of the **Patient Enrollment Form**

Step 2:

Fill out the patient sections of the **Prescription Authorization and Patient Referral Form**

Once your healthcare provider submits this form, **you will be enrolled in the ONWARD™ Support Program.**

Personalized support will be available to you at **1-888-964-3649**. Plus, you will receive a welcome call from your Care Coordinator, who can help you navigate the next steps.

Step 3:

Give these forms to your loved one's healthcare provider when you talk with them about FINTEPLA

Safety and REMS

The FINTEPLA Risk Evaluation and Mitigation Strategy (REMS) Program was **created with your loved one's safety in mind**. It requires that they have heart checkups (echocardiograms) once before starting treatment with FINTEPLA, again every 6 months during treatment, and once 3 to 6 months after their last dose. This helps manage potential safety concerns.

What is REMS?
It is a drug safety program that the US Food and Drug Administration (FDA) requires for certain medicines with serious safety concerns. Drug companies and healthcare providers must take extra steps to make sure the benefits of using the drug are more than the risks. The FDA must approve these steps as part of the REMS program.

Why REMS?
FINTEPLA is available only through the FINTEPLA REMS due to the risk of problems with valves in the heart (valvular heart disease) and high blood pressure in the arteries of the lungs (pulmonary arterial hypertension). In the past, some adults who took fenfluramine, the active ingredient in FINTEPLA, developed problems with valves in the heart and high blood pressure in the arteries of the lungs.

The FINTEPLA REMS can help to identify any problems before symptoms develop.

None of the 341 patients with Dravet syndrome or 262 patients with LGS who took FINTEPLA during the clinical studies developed problems with their heart valves that caused valvular heart disease or high blood pressure in the arteries of the lungs, including patients treated for up to 3 years.

Indication

- FINTEPLA is a prescription medicine used to treat seizures associated with Dravet syndrome and Lennox-Gastaut syndrome in patients 2 years of age and older.
- It is not known if FINTEPLA is safe and effective in children less than 2 years of age.

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Important Safety Information

FINTEPLA can cause serious side effects, including:

1. **Problems with the valves in the heart (valvular heart disease) and high blood pressure in the arteries of the lungs (pulmonary arterial hypertension)** have been associated with fenfluramine, the active ingredient in FINTEPLA. Your healthcare provider will do a test called an echocardiogram to check your heart and to evaluate for high blood pressure in the arteries of the lungs before you start taking FINTEPLA, again every 6 months during treatment, and one time 3 to 6 months after you take your last dose of FINTEPLA.

   Call your healthcare provider right away if you develop any of these signs and symptoms of heart or lung problems during treatment with FINTEPLA:

   - shortness of breath
   - tiredness or weakness, especially with increased activity
   - lightheadedness or fainting
   - swollen ankles or feet
   - chest pain
   - sensations of a rapid, fluttering heartbeat (palpitations)
   - irregular pulse
   - bluish color of your lips and skin (cyanosis)

   Because of the risk of heart valve problems (valvular heart disease) and high blood pressure in arteries of lungs (pulmonary arterial hypertension), FINTEPLA is only available through a restricted program called the FINTEPLA Risk Evaluation and Mitigation Strategy (REMS) Program. Before you or your child receives FINTEPLA, your healthcare provider or pharmacist will make sure you understand how to take FINTEPLA safely. If you have any questions about FINTEPLA, ask your healthcare provider, visit www.FinteplaREMS.com, or call 1-877-964-3649.

2. **Decreased appetite and decreased weight.** Decreased appetite and decreased weight are both serious and common side effects of FINTEPLA in people with Dravet syndrome (DS) or Lennox-Gastaut syndrome (LGS).
   - Your weight should be checked regularly during your treatment with FINTEPLA.
   - Your healthcare provider may need to make changes to your FINTEPLA dose if your weight decreases. In some cases, FINTEPLA may need to be stopped.

3. **Sleepiness, sedation, and lack of energy (lethargy).** These are both serious and common side effects of FINTEPLA in people with Dravet syndrome (DS) or Lennox-Gastaut syndrome (LGS). Taking FINTEPLA with central nervous system (CNS) depressants, including alcohol, may increase sleepiness. **Do not** drive, operate heavy machinery, or do other dangerous activities until you know how FINTEPLA affects you.

4. **Like all other antiepileptic drugs, FINTEPLA may cause suicidal thoughts or actions** in a very small number of people (about 1 in 500).

   Call your healthcare provider right away if you have any of these symptoms, especially if they are new, worse, or worry you:

   - thoughts about suicide or dying
   - trouble sleeping (insomnia)
   - attempts to commit suicide
   - new or worse irritability
   - new or worse depression
   - acting aggressive, being angry or violent
   - new or worse anxiety
   - acting on dangerous impulses
   - feeling agitated or restless
   - an extreme increase in activity and talking (mania)
   - panic attacks
   - other unusual changes in behavior or mood

   How can I watch for early symptoms of suicidal thoughts and actions?
   - Pay attention to any changes, especially sudden changes, in mood, behaviors, thoughts, or feelings.
   - Keep all follow-up visits with your healthcare provider as scheduled.

   Suicidal thoughts or actions can be caused by things other than medicines. If you have suicidal thoughts or actions, your healthcare provider may check for other causes.

5. **Do not stop taking FINTEPLA without first talking to your healthcare provider.** Stopping a seizure medicine such as FINTEPLA can suddenly cause you to have seizures more often or seizures that do not stop (status epilepticus).

   Call your healthcare provider between visits as needed, especially if you are worried about symptoms.

Please see full Prescribing Information, including Medication Guide, for additional Important Safety Information on FINTEPLA at Fintepla.com.

Continued on next page.

Important Safety Information *(continued)*

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Do not take FINTEPLA if you:

- are allergic to fenfluramine or any of the ingredients in FINTEPLA. See below for a complete list of ingredients in FINTEPLA.
- are taking or have stopped taking medicines called monoamine oxidase inhibitors (MAOIs) in the last 14 days. This may cause a serious or life-threatening problem called **serotonin syndrome**. If you are not sure whether or not you are taking one of these medicines, contact your healthcare provider.

Before taking FINTEPLA, tell your healthcare provider about all of your medical conditions, including if you:

- have heart problems
- have or have had weight loss
- have or have had depression, mood problems, or suicidal thoughts or behavior
- have kidney problems
- have liver problems
- are pregnant or plan to become pregnant. Tell your healthcare provider right away if you become pregnant while taking FINTEPLA. You and your healthcare provider will decide if you should take FINTEPLA while you are pregnant.
  - If you become pregnant while taking FINTEPLA, talk to your healthcare provider about registering with the North American Antiepileptic Drug Pregnancy Registry. You can enroll in this registry by calling 1-888-233-2334 or go to www.aedpregnancyregistry.org. The purpose of this registry is to collect information about the safety of antiepileptic drugs during pregnancy.
- are breastfeeding or plan to breastfeed. It is not known if FINTEPLA passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby while taking FINTEPLA.

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

Know the medicines you take. Keep a list of them to show your healthcare provider or pharmacist when you get a new medicine.

How should I take FINTEPLA?

- Read the **Instructions for Use** for information on the right way to use FINTEPLA.
- Take FINTEPLA exactly as your healthcare provider tells you to take it.
- Your healthcare provider will tell you how much FINTEPLA to take and when to take it.
- FINTEPLA may be taken with or without food.
- Measure your dose of FINTEPLA using the dosing syringe that is provided by the pharmacy. Do not use a household teaspoon or tablespoon.
- FINTEPLA can be given through gastric and nasogastric feeding tubes.

What should I avoid while taking FINTEPLA?

- **Do not** drive, operate heavy machinery, or do other dangerous activities until you know how FINTEPLA affects you. FINTEPLA may cause you to feel sleepy.

What are the possible side effects of FINTEPLA?

FINTEPLA may cause serious side effects, including:

- See **"FINTEPLA can cause serious side effects" above**
  - **Serotonin syndrome.** Serotonin syndrome is a life-threatening problem that can happen in people taking FINTEPLA, especially if FINTEPLA is taken with certain other medicines including: anti-depressant medicines called SSRIs, SNRIs, TCAs, and MAOIs; tryptophan; lithium; antipsychotics; St. John's Wort; dextromethorphan; tramadol.

    Call your healthcare provider right away if you have any of the following symptoms of serotonin syndrome:

    - mental status changes such as seeing things that are not there (hallucinations), agitation, or coma
    - changes in blood pressure
    - tight muscles
    - fast heartbeat
    - nausea, vomiting, diarrhea
    - high body temperature
    - trouble walking

Important Safety Information *(continued)*

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- **High blood pressure (hypertension).** Hypertension is both a serious and common side effect. FINTEPLA can cause your blood pressure to increase even if you have never had high blood pressure before. Your healthcare provider will check your blood pressure while you are taking FINTEPLA.
- **Increased pressure in your eyes (glaucoma).** Symptoms of glaucoma may include:
  - red eyes
  - seeing halos or bright colors around lights
  - nausea or vomiting
  - decreased vision
  - eye pain or discomfort
  - blurred vision

If you have any of these symptoms, call your healthcare provider right away.

- **The most common side effects of FINTEPLA when used to treat Dravet syndrome (DS) include:**
  - decreased appetite
  - diarrhea
  - low energy
  - respiratory infection
  - decreased weight
  - fever
  - constipation
  - abnormal echocardiogram
  - sleepiness
  - problems with movement, balance, and walking
  - increased drooling
  - increased blood pressure
  - vomiting
  - falls
  - seizures that do not stop
  - weakness
- **The most common side effects of FINTEPLA when used to treat Lennox-Gastaut syndrome (LGS) include:**
  - diarrhea
  - tiredness
  - vomiting
  - sleepiness
  - decreased appetite

These are not all the possible side effects of FINTEPLA. For more information, ask your healthcare provider or pharmacist. Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

Keep FINTEPLA and all medicines out of the reach of children.

General information about the safe and effective use of FINTEPLA.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use FINTEPLA for a condition for which it was not prescribed. Do not give FINTEPLA to other people, even if they have the same symptoms that you have. It may harm them.

What are the ingredients in FINTEPLA?

Active ingredient: fenfluramine hydrochloride

Inactive ingredients: cherry flavor, citric acid ethylparaben, hydroxyethylcellulose, methylparaben, potassium citrate, sucralose, and water.

FINTEPLA contains no ingredient made from gluten-containing grain (wheat, barley, or rye) and contains not more than 0.1% of carbohydrates, which is from the cherry flavoring.

Please see full Prescribing Information, including Medication Guide, for additional Important Safety Information on FINTEPLA at Fintepla.com.

ONWARD is provided as a service of UCB and is intended to support the appropriate use of UCB medicines.
ONWARD may be amended or canceled at any time without notice. Some program and eligibility restrictions may apply.