

CALLIE, LIVING WITH DRAVET SYNDROME (DS), LAUGHING WITH HER FAMILY

WHEN CALLIE *LIVES OUT LOUD*,  
**THAT'S THE SOUND  
OF PROFOUND**  
MADE POSSIBLE BY FINTEPLA



Use this guide to see what's possible with FINTEPLA, including information about seizure reduction, resources, and support.

**Fintepla**<sup>®</sup>  
(fenfluramine)  
2.2 mg/mL oral solution

## 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.

## 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 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 11-13 and full Prescribing Information, including Medication Guide.**



GIOVANNI, LIVING WITH  
DRAVET SYNDROME

FIND RESOURCES ABOUT DRAVET SYNDROME AT  
[SHINEFORWARDWITHDRAVET.COM](https://www.shineforwardwithdravet.com)

# Understanding Dravet syndrome and the risks of uncontrolled seizures

Dravet syndrome is a rare type of epilepsy that starts as early as infancy, with frequent, uncontrolled seizures that are difficult to treat and may take a toll on everyone involved.

Some of the challenges facing families who have a loved one with Dravet syndrome include:

44%

**of patients still experience life-threatening seizures,** despite taking antiseizure medicines (ASMs)

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**Devastating consequences** on a child's growth and development

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~6x

**Higher risk of SUDEP** in patients with Dravet syndrome than in other forms of epilepsy

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**Unwanted side effects** from taking multiple ASMs

SUDEP, sudden unexpected death in epilepsy.

# What makes FINTEPLA different from other ASMs?

Here are some of the reasons to consider talking with your loved one's healthcare team about FINTEPLA:



## Profound seizure reduction

Significantly reduces seizures associated with DS. (pg 5)



## Well-established safety profile

Approved by the US FDA for seizures associated with Dravet syndrome and Lennox-Gastaut syndrome (LGS). FINTEPLA was approved based on the safety and efficacy results from clinical trials. (pg 6)



## Fits into your loved one's treatment plan

No adjustments to baseline ASMs are needed as FINTEPLA works differently from other ASMs. FINTEPLA has not shown a meaningful impact on how the body interacts with other ASMs. (pg 9)

Since the approval of FINTEPLA in June 2020 for seizures associated with Dravet syndrome and March 2022 for seizures associated with LGS, more than 10,000 patients worldwide have been prescribed FINTEPLA.

Watch a video about how FINTEPLA can fit into your loved one's current treatment plan at [FINTEPLA.com](https://www.fintepla.com).



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**FINTEPLA can cause serious side effects, including:**

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# Profound long-term seizure reduction is possible

In the medical community, anything equal to or greater than a 75% reduction in monthly seizures is considered a profound result.

## Study 1



In a 14-week clinical study of people taking 0.7 mg/kg/day\*

**FINTEPLA**  
**↓ REDUCED**  
**MONTHLY SEIZURES BY 79%**  
— THIS IS COMPARED WITH ONLY —  
**16% FOR PATIENTS TAKING A PLACEBO†**

**1 IN 2 PEOPLE TAKING FINTEPLA HAD AT LEAST**

**21 DAYS IN A ROW SEIZURE FREE**  
— THIS IS COMPARED WITH ONLY —  
**8 DAYS FOR THOSE TAKING A PLACEBO**

\*Adjusted for placebo, FINTEPLA reduced monthly seizures by 70% for patients taking 0.7 mg/kg/day. This percentage takes into account the placebo effect, which is when people feel better because they've taken a different treatment and not necessarily because of the treatment's efficacy.

†Patients added FINTEPLA (0.7 mg/kg/day) or placebo to their current antiseizure treatment plans during the study. Results may vary.

## IMPORTANT SAFETY INFORMATION (cont.)

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

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## Understanding the clinical studies

The safety and effectiveness of FINTEPLA were evaluated in 2 clinical studies of patients with Dravet syndrome aged 2 years and older. Study 1 had 117 patients and Study 2 had 85 patients.

Study 1 compared improvement in monthly seizure frequency of 2 different doses of FINTEPLA versus placebo over a 14-week treatment period.



### Before joining FINTEPLA Study 1, patients had:

- **Uncontrolled seizures:** 6 or more convulsive seizures over the course of 6 weeks
- **A current treatment plan for seizures:** 1 to 4 ASMs or treatments, including use of a vagal nerve stimulator or a ketogenic diet



### In Study 1, patients were randomly placed into 1 of 3 groups:

- Patients taking 0.2 mg/kg/day of FINTEPLA (n=38)
- Patients taking 0.7 mg/kg/day of FINTEPLA (n=40)
- Patients taking placebo (n=39)

**All patients added either FINTEPLA or placebo to their existing treatment plans.**

### Patients stayed on FINTEPLA

Over 3 years, 341 patients took FINTEPLA in the clinical studies, with **138 patients taking FINTEPLA for more than 2 years.**



## IMPORTANT SAFETY INFORMATION (cont.)

Because of the risk of heart valve problems (valvular heart disease) and high blood pressure in the arteries of the lungs (pulmonary arterial hypertension), FINTEPLA is only available through a restricted program called the FINTEPLA Risk Evaluation and Mitigation Strategy (REMS).

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](http://www.FinteplaREMS.com), or call 1-877-964-3649.

**Please see full Important Safety Information on pages 11-13 and full Prescribing Information, including Medication Guide.**

## FINTEPLA: Long-term results

Throughout this 36-month, long-term, open-label extension study, most patients maintained the seizure reduction they experienced in the clinical studies.

From the original clinical studies:

**94%** OF PATIENTS CONTINUED WITH FINTEPLA  
 AND PARTICIPATED IN A LONG-TERM,  
 OPEN-LABEL EXTENSION STUDY

In this open-label extension study:



**Patients added FINTEPLA (0.7 mg/kg/day) to their current antiseizure treatment plans.**

Since this was an open-label, flexible-dose study, no conclusions of efficacy or safety should be made based on these results. Results may vary. An open-label study means patients knew they were being treated with FINTEPLA and not a placebo.

**The most common side effects reported in the long-term clinical study:**

- Fever
- Nasopharyngitis
- Decreased appetite
- Blood glucose decreased
- Diarrhea
- Abnormal echo\*
- Upper respiratory infection
- Seizure
- Influenza
- Vomiting
- Ear infection

Most patients with Dravet syndrome resumed expected weight gains during the open-label extension study.

\*These abnormal echo findings included mild or trace amounts of blood leaking backwards through heart valves.

### IMPORTANT SAFETY INFORMATION (cont.)

**2. Decreased appetite and decreased weight.** Decreased appetite and decreased weight are serious and common side effects of FINTEPLA.

- 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.

**Please see full Important Safety Information on pages 11-13 and full Prescribing Information, including Medication Guide.**

# FINTEPLA<sup>®</sup> REMS was designed with your loved one's safety in mind



## **FINTEPLA is available only through FINTEPLA REMS**

due to the risk of potential problems with valves in the heart (valvular heart disease) and high blood pressure in the arteries of the lungs (pulmonary arterial hypertension).



## Your loved one's doctor **will proactively order heart tests**

**(echocardiograms)** before, during, and one time after the last dose to make sure there are no heart issues.



Help is available through ONWARD<sup>®</sup> with identifying where to receive these required echocardiograms, either at a doctor's office or at home.



**Since the approval** of FINTEPLA in June 2020 for seizures associated with Dravet syndrome and March 2022 for seizures associated with LGS, **more than 10,000 patients worldwide have been prescribed FINTEPLA.**

### **The most common side effects reported in clinical trials:**

- 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

These are not all of 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 does not go away.

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

REMS, Risk Evaluation and Mitigation Strategy.

**Please see full Important Safety Information on pages 11-13 and full Prescribing Information, including Medication Guide.**

MILLER LAUGHING AND  
PLAYING IS PROFOUND

HOW FINTEPLA CAN

# EASILY FIT INTO YOUR LOVED ONE'S ROUTINE

## Why FINTEPLA fits:

- ✓ No adjustments to baseline ASMs necessary; add FINTEPLA without disruptions to current ASMs
- ✓ FINTEPLA can be taken by mouth with or without food
- ✓ FINTEPLA is compatible with gastric and nasogastric feeding tubes
- ✓ Dosing is flexible based on how well your loved one responds to and tolerates FINTEPLA
- ✓ FINTEPLA can be taken with other treatments such as vagal nerve stimulation or a ketogenic diet

Watch a video that shows how FINTEPLA can fit into current treatment plans at [FINTEPLA.com](https://www.fintepla.com).



## IMPORTANT SAFETY INFORMATION (cont.)

- 3. Sleepiness, sedation, and lack of energy (lethargy).** These are serious and common side effects of FINTEPLA. 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.

Please see full Important Safety Information on pages 11-13 and full [Prescribing Information](#), including [Medication Guide](#).

# FINTEPLA support along the way

ONWARD<sup>®</sup> provides dedicated one-on-one support to help move you forward.



Fintepla<sup>®</sup>  
(fenfluramine)  
2.2 mg/mL oral solution

## FINTEPLA Clinical Nurse Educators (CNEs)

are nurses and experts in Dravet syndrome who answer questions and provide treatment education for families starting FINTEPLA.\*



Get in touch with a Clinical Nurse Educator by calling  
1-833-GO-DS-LGS (1-833-463-7547).

Call any time from 7:30 AM to 4:30 PM Central Time, Monday through Friday, and ask to talk with a Clinical Nurse Educator.

\*Clinical Nurse Educators cannot provide medical advice or make treatment recommendations. They can only provide information about FINTEPLA. Decisions regarding your loved one's health and the treatment of their condition should be made with their healthcare provider.

Visit [FINTEPLA.com](https://www.fintepla.com) for more info about support to help get you started on FINTEPLA.

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.

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

Because of the risk of heart valve problems (valvular heart disease) and high blood pressure in the arteries of the lungs (pulmonary arterial hypertension), FINTEPLA is only available through a restricted program called the FINTEPLA Risk Evaluation and Mitigation Strategy (REMS). 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](http://www.FinteplaREMS.com), or call 1-877-964-3649.

- 2. Decreased appetite and decreased weight.** Decreased appetite and decreased weight are serious and common side effects of FINTEPLA.
  - 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 serious and common side effects of FINTEPLA. 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:**

**Please see full Important Safety Information on pages 11-13 and full Prescribing Information, including Medication Guide.**

## IMPORTANT SAFETY INFORMATION (cont.)



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).

### **Do not take FINTEPLA if you:**

- are allergic to fenfluramine or any of the ingredients in FINTEPLA. See the Medication Guide 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 your medical conditions, including** heart problems; weight loss; depression, mood problems, or suicidal thoughts or behavior; kidney problems; liver problems; are pregnant or plan to become pregnant; are breastfeeding or plan to breastfeed.

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

### **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, or diarrhea; high body temperature; trouble walking.

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- **High blood pressure (hypertension).** Hypertension is a serious and common side effect. FINTEPLA can cause your blood pressure to increase even if you have never had high blood pressure before.
- **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 patients with 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 patients with 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.**

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



# WHAT SOUND OF PROFOUND COULD FINTEPLA BRING FOR YOUR FAMILY?

RYKER, LIVING WITH DS,  
BOUNCING A BASKETBALL

Visit [FINTEPLA.com](https://www.fintepla.com) to see more stories of families like yours.

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 Inspired by **patients**.  
Driven by **science**.

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