



Fintepla®
(fenfluramine)
2.2 mg/mL oral solution

WHAT TO KNOW ABOUT ECHOCARDIOGRAMS (ECHO TESTS)

A guide for your loved one's first echocardiogram

Scarlett, living with
Lennox-Gastaut
syndrome (LGS)

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

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 7-11 and full [Prescribing Information](#), including [Medication Guide](#), for additional Important Safety Information on FINTEPLA.

FINTEPLA® REMS was designed with your loved one's safety in mind

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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 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.**

REMS, Risk Evaluation and Mitigation Strategy.

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 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.

Click to watch a video about safety and why monitoring is needed

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What is an echocardiogram?

An echocardiogram (also called an “echo test”) is a noninvasive test that helps healthcare providers monitor someone’s heart health. The test is done with an ultrasound device, similar to the ones used for sonograms during pregnancy.

Echo tests take about an hour to complete. Your loved one has to remain still during the testing.

An echo test uses sound waves (an ultrasound) to take pictures of your loved one’s heart.

The test uses a few different tools:



A sonographer will place a few stick-on patches onto your loved one’s chest to record their heart’s activity. These patches are called **electrodes**.



Next, the person doing the echo test will send sound waves into your loved one’s chest using a wand-like device called a **transducer**.



Ultrasound gel is used too. This helps the sound waves from the transducer reach your loved one’s heart.



Finally, an **ultrasound computer** will turn the sound waves into pictures of your loved one’s heart.

Once your loved one’s first echo test is complete, make sure to contact your healthcare provider to let them know. They should receive the echo test results in a few days. Based on the results, you and your healthcare provider will decide if starting treatment with FINTEPLA is right for your loved one.



“Fin and Willow Get an Echocardiogram”

Click here to download a free booklet where lovable characters walk the whole family through this important test.

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How should we prepare for the echo test?

There will be moments during the test when you can help make your loved one more comfortable. But when images are being taken, your loved one will need to lie still. If your loved one typically has a hard time keeping still, your healthcare provider may talk to you about some ways to help, like giving them a mild sedative.

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On the day of the echo test:



Have your loved one eat and drink normally.



Consider bringing a comforting toy, a tablet, or a favorite story to read to your loved one during the test.



Dress your loved one in a shirt that can be easily taken off or unbuttoned for the test.



Think about bringing a blanket in case your loved one gets cold, and a pillow to lie on.



Avoid putting lotions, creams, or powders on your loved one's chest.



Watch a video for tips on how to prepare for your loved one's first echocardiogram at [Fintepla.com](https://www.fintepla.com).

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From echo test to treatment: How do we get there?

We know you're eager for what's next, and we want to help you get there.

Here's how the process will work:



Once the echo test is complete, the results will be sent to your loved one's healthcare provider.

The healthcare provider will review the test results with you and then send the information to the ONWARD® Support Program.

Based on the results of the echo test, you and your loved one's healthcare provider will decide if treatment with FINTEPLA is right for your loved one.

Your healthcare provider's office will contact ONWARD about processing your loved one's FINTEPLA prescription for shipment.

Make sure to bring the Echocardiogram Assessment Backgrounder form to the appointment for the technician to complete; the form can be found in your FINTEPLA Welcome Kit.

SELECT 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
- 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)


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ONWARD[®] has your back

If you decide to enroll in the ONWARD Support Program, you will be matched with a Care Coordinator. They will help you throughout the process of getting your loved one started with FINTEPLA.

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Need help paying for your loved one's echocardiogram?

The ONWARD Copay Assistance Program may be able to help eligible families and patients with commercial insurance pay for costs related to FINTEPLA REMS and required echocardiograms. Full eligibility terms and conditions apply.



Don't have access to a facility that does echo tests?

Your ONWARD Care Coordinator can help with finding an echo facility in your area. For eligible patients prescribed FINTEPLA who are unable to access one, they can help organize at-home echo tests. Learn more about the UCB At-home Echo option at [FINTEPLA.com/AtHomeEcho](https://www.fintepla.com/AtHomeEcho).



Your Care Coordinator is ready to help

Don't hesitate to reach out with any questions you may have.

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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Important Safety Information

INDICATION

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- It is not known if FINTEPLA is safe and effective in children less than 2 years of age.

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 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
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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, 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:** 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.

Please see full Important Safety Information on pages 7-11 and full Prescribing Information, including Medication Guide, for additional Important Safety Information on FINTEPLA.

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.

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IMPORTANT SAFETY INFORMATION (cont.)

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.

- **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 logo for Fintepla, featuring the brand name in a serif font with a registered trademark symbol, followed by the generic name (fenfluramine) and the concentration (2.2 mg/mL oral solution) in a smaller sans-serif font. The logo is set against a white background with a purple border.

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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.

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Emma, living with
Dravet syndrome

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Questions about the echocardiogram?

You can also talk to a FINTEPLA Care Coordinator by calling **1-888-964-3649, Monday through Friday, 7 AM-7 PM Central Time.** They can provide live, individualized support and address your questions about FINTEPLA and FINTEPLA REMS.

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

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