What to Know About **Echocardiograms (Echo Tests)**

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 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 8-13 and full Prescribing Information, including Medication Guide, for additional Important Safety Information on FINTEPLA.

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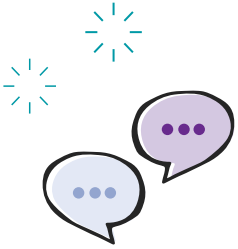
(fenfluramine)
2.2 mg/mL oral solution

What is an **echocardiogram?**

FINTEPLA has a Risk Evaluation and Mitigation Strategy (REMS) Program that requires periodic cardiac monitoring via echocardiogram to detect problems with the valves in the heart and high blood pressure in the arteries of the lungs. An echocardiogram (also called an "echo test") is a non-invasive test that helps healthcare providers see how healthy someone's heart is. The test is done with an ultrasound device, similar to the ones used for sonograms during pregnancy.

Echo tests are non-invasive. They take about an hour to complete. Your loved one has to remain still during the testing.



Visit Fintepla.com to watch a video about safety.

Important Safety Information

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Why does my loved one need an **echocardiogram?**

Visit Fintepla.com to watch a video about the FINTEPLA REMS Program.

Determining your loved one's baseline heart health with an echo test before starting on FINTEPLA is an essential part of treatment.

However, you probably have a lot of questions about why an echo test is needed in the first place.

The FINTEPLA Risk Evaluation and Mitigation Strategy (REMS) Program was created with your loved one's safety in mind. It requires that they have regular heart checkups (echocardiograms) to help manage potential safety concerns.

What it is

The REMS program 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 it matters

FINTEPLA is only available through the FINTEPLA REMS Program 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 their heart valves or high blood pressure in the arteries of their lungs.

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

You and your healthcare provider will discuss the results of the echo test to decide whether to begin or continue FINTEPLA.

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How does an **echo test work?**

An echo test uses sound waves (an ultrasound) to take pictures of your loved one's heart. The test uses a few different tools:

Electrodes: A sonographer will place a few of these stick-on patches onto your loved one's chest to record their heart's activity

Transducer: The person doing the echo test will move this wand-like device around your loved one's chest. It sends sound waves into your loved one's chest

Ultrasound gel: This is spread onto the transducer. It helps the sound waves from the transducer reach your loved one's heart

Ultrasound computer: This machine turns the sound waves into pictures of your loved one's heart

Need help paying for your loved one's echocardiogram?

- The ONWARD™ Echocardiogram Copay Support Program may be able to help eligible families and patients pay for costs related to FINTEPLA treatment
- Covered echo expenses include copays, deductibles, and coinsurance

Your Care Coordinator is ready to help; don't hesitate to reach out with any questions you may have. Your Care Coordinator is standing by, ready to guide you through every step of your loved one's treatment with FINTEPLA.

Important Safety Information *(continued)*

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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How should we prepare for the echo test?

On the day of the echo test:

Visit Fintepla.com to see a video with tips for your loved one's first echo test.

Have your loved one eat and drink normally

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

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

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

Think about bringing a blanket in case they get cold, and a pillow to lie on

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.

Important Safety Information *(continued)*

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.

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What is included in the **echo test results?**

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Once your loved one's first echo test is complete, make sure to contact your Care Coordinator or healthcare provider to let them know. Your healthcare provider should receive the echo test results in a few days.

Here's what to keep in mind about the results:

- Regular monitoring with an echo test can help detect heart problems before they start
- Sometimes, echo test results include a type of abnormal reading that is commonly seen in healthy people; if necessary, your healthcare provider can explain more about this kind of result
- A trained healthcare provider will interpret the results of the echo test and provide you with a summary of the findings
- Based on results of the echo test, you and your healthcare provider will decide if treatment with FINTEPLA is right for your loved one

Did patients in the FINTEPLA clinical studies develop problems with the heart valves or high blood pressure in the arteries of the lungs?

None of the 262 patients with LGS or 341 patients with Dravet syndrome 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 (pulmonary arterial hypertension), including patients treated for up to 3 years. However, the FINTEPLA REMS Program can help to identify any problems before symptoms develop.

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

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We know you're eager for what's next, and we want to help you get there. Here's how the process will work:

1. Once the echo test is complete, the results will be sent to your loved one's healthcare provider
2. The healthcare provider will review the test results with you and then send the information to the ONWARD Support Program
3. 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
4. Your healthcare provider's office will contact ONWARD about processing your loved one's FINTEPLA prescription for shipment

Don't forget to:

1. **Let your Care Coordinator know the date of the test** by contacting ONWARD at 1-888-964-3649, Monday through Friday, 7 AM - 7 PM Central Time
2. **Bring the Echocardiogram Assessment Backgrounder form with you to the test** for the technician to complete; the form can be found in your FINTEPLA Welcome Kit

Important Safety Information *(continued)*

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.

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Important Safety Information

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Indication

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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.

Continued on next page.

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

Important Safety Information *(continued)*

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.

Continued on next page.

Important Safety Information *(continued)*

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.

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.

Continued on next page.

Important Safety Information *(continued)*

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.

Continued on next page.

Important Safety Information *(continued)*

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

- **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

Continued on next page.

Important Safety Information *(continued)*

- **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.

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Questions about the echocardiogram?

Please contact your Care Coordinator by calling 1-888-964-3649, **Monday through Friday, 7 AM-7 PM Central Time**.

You can also talk to a FINTEPLA Clinical Nurse Educator, who can provide live, individualized support and address your questions about FINTEPLA and the FINTEPLA REMS Program by calling 1-833-GO-DS-LGS (1-833-463-7547).

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