For seizures associated with Lennox-Gastaut syndrome) in patients ages 2 and older



Aaron, living life with LGS

Let in more life with fewer seizures

Reimagine what's possible with FINTEPLA

Indication

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- 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:

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.

Making more possible with Lennox-Gastaut syndrome (LGS)

Day-to-day management of LGS can already be overwhelming. Advocating for your loved one and weighing treatment options can bring even more complexity, and it is natural to wonder if anything else is possible.

That's where FINTEPLA fits in:



FINTEPLA and your loved one's seizures

Significant and maintained seizure reduction across seizure types commonly experienced in LGS.

Learn more on pages 4-6



Safety is our priority

The FINTEPLA Risk Evaluation and Mitigation Strategy (REMS) Program 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.

> Visit <u>Fintepla.com</u> to watch a video about safety.

Learn more on page 10

FINTEPLA works with current treatment plans

You may not have to worry about adjusting current antiseizure treatments.

Visit <u>Fintepla.com</u> to watch a video that shows how FINTEPLA can fit into current treatment plans.

Learn more on page 8



Get access to individualized resources and medical expertise through the ONWARD™ Support Program.

Learn more on pages 12-13

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, including patients treated for up to 3 years.

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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.





Aaron, living life with LGS

Results with FINTEPLA

Learn more on page 4 🕨

FINTEPLA Dosing Learn more on page 8 >

FINTEPLA REMS Program Learn more on page 10 >

ONWARD™ Support Program

Learn more on pages 12-13 ▶



Patients with LGS had fewer seizures with FINTEPLA

FINTEPLA: Significant and maintained seizure reduction across seizure types commonly experienced in LGS

In a 14-week clinical study:

FINTEPLA REDUCED MONTHLY DROP 24% COMPARED WITH 9% FOR PATIENTS TAKING PLACEBO Patients added either FINTEPLA (0.7 mg/kg/day) or placebo to their current

Patients added either FINTEPLA (0.7 mg/kg/day) or placebo to their current antiseizure treatment plans. In the clinical study, 0.7 mg/kg/day was the only dose of FINTEPLA to significantly reduce monthly drop seizures. Results may vary.

Seizure reduction was maintained throughout the 14-week study period.

Patients experienced seizure reduction across multiple seizure types



Select 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

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- 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)

FINTEPLA was studied in patients experiencing serious and hard-to-treat seizures.



263 patients with LGS enrolled in the clinical study. It compared monthly drop seizure reduction between 2 different doses of FINTEPLA (0.7 mg/kg/day and 0.2 mg/kg/day) and placebo over a 14-week treatment period.

All patients in the clinical study were between ages 2 and 35 (with 29% over age 18).

Before the Study



Patients had been treated with an average of 7 other antiseizure medicines.



Patients were having at least 8—and an average of 194—seizures that resulted in drops or falls or injuries per month.

During the Study



All patients were being treated with 1 to 4 other antiseizure medicines or treatments. The most common medicines were clobazam, lamotrigine, and valproate. Treatment plans included the ketogenic diet.

Some patients had interventional procedures, such as vagal nerve stimulation or a corpus callosotomy.

Patients were randomly placed into 1 of 3 groups where they took 0.7 mg/kg/day of FINTEPLA, 0.2 mg/kg/day of FINTEPLA, or placebo. All patients added FINTEPLA or placebo to their current antiseizure treatment plans.

In the clinical study, 0.7 mg/kg/day was the only dose of FINTEPLA to significantly reduce monthly drop seizures.

Select 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 <u>1-877-964-3649</u>.



Throughout the 15-month, long-term, open-label extension study of FINTEPLA, most patients maintained the seizure reduction they experienced in the clinical study.

Since this was an open-label, flexible-dose study, no conclusions of efficacy should be made based on these results. Results may vary.

Hayden, living life with LGS, and his brother

(fenfluramine) mL oral solution

Select Important Safety Information (continued)

- 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.

Long-term study results



After the original clinical study:



Patients added FINTEPLA (up to 0.7 mg/kg/day) to their current antiseizure treatment plans. Since this was an open-label, flexible-dose study, no conclusions of efficacy should be made based on these results. Results may vary.

Select Important Safety Information (continued)

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.



FINTEPLA can fit into current treatment plans



In most cases, FINTEPLA can be added without disrupting current treatments or compromising progress made with them.**

- FINTEPLA is a twice-daily oral solution that is cherry flavored and **can be taken with or without food**
- There are no dietary restrictions while taking FINTEPLA—including being on the ketogenic diet
- FINTEPLA is compatible with feeding tubes

Visit <u>Fintepla.com</u> to watch a video that shows how FINTEPLA can fit into current treatment plans.

Though your loved one's current antiseizure treatment plan does not need to be adjusted when adding FINTEPLA, the maximum daily dose of FINTEPLA may need to be adjusted if your loved one is also taking certain other therapeutic medicines or has certain other medical conditions.

Patients with LGS adding FINTEPLA should start at the 0.2 mg/kg/day dose and increase weekly based on tolerability to a maximum recommended maintenance dose of 0.7 mg/kg/day.

*Your loved one should not take FINTEPLA if they are allergic to fenfluramine or any other ingredients in FINTEPLA, or if they have taken medicines called monoamine oxidase inhibitors (MAOIs) in the last 14 days. This may cause a serious or life-threatening problem called serotonin syndrome. If there is uncertainty about whether they have taken one of these medicines, talk to your healthcare provider.

[†]Talk to your loved one's healthcare provider about all of their medical conditions and medicines they take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

> Hayden, living life with LGS, and his family

Clinical Global Impression-Improvement (CGI-I)



At the end of the 14-week study of FINTEPLA for LGS, each patient's healthcare provider and parent or caregiver compared the patient's overall functioning to how it was before starting treatment with FINTEPLA. Both groups ranked overall functioning using CGI-I, a 7-point scale where 1 is Very Much Improved and 7 is Very Much Worse.



More healthcare providers and caregivers saw an improvement* on the CGI-I scale for patients treated with FINTEPLA than patients treated with placebo.

*A score of 1 to 3 means improvement; a score of 4 means no change; a score of 5 to 7 means worsening.

Select Important Safety Information (continued)

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



The FINTEPLA Risk Evaluation and Mitigation Strategy (REMS) Program

The FINTEPLA REMS 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.

Visit <u>Fintepla.com</u> to watch a video about the FINTEPLA REMS.

What it is

The FINTEPLA REMS 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 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 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, including patients treated for up to 3 years.

Select Important Safety Information (continued)



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.



Common side effects of FINTEPLA



The most common side effects of FINTEPLA when used to treat LGS include:

- Diarrhea
- Tiredness
- Vomiting
- Sleepiness
- Decreased appetite

About half of patients with LGS resumed expected weight gain during the open-label extension study.

Only 6% of patients discontinued treatment due to side effects.





Select 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.

FINTEPLA support along the way

Whether you simply have a few questions about FINTEPLA or have a loved one who is about to start treatment, ONWARD provides dedicated one-on-one support to help move you forward.



Considering FINTEPLA?

ONWARD has resources to help get you going in the right direction.

FINTEPLA Clinical Nurse Educators (CNEs) are registered nurses and experts in Dravet syndrome and LGS who answer any questions you have and provide treatment education for families before starting FINTEPLA.* They can:

- Prepare you for conversations with your loved one's healthcare provider
- Discuss results of the FINTEPLA clinical studies and what they may mean for your family
- Answer your questions about the FINTEPLA REMS Program
- Educate you on financial support programs for access to FINTEPLA treatment and echocardiogram tests

*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.

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

Scan this QR code with your smartphone to add your FINTEPLA CNE's phone number to your contacts.



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

Once you start FINTEPLA



Visit <u>Fintepla.com</u> to watch a video about available financial support programs. ONWARD offers comprehensive support from day 1 to simplify your journey.

Care Coordinators are registered nurses trained in LGS and treatment with FINTEPLA. Once enrolled in ONWARD, every family is given a dedicated Care Coordinator who will reach out and help you and your loved one start and stay on treatment.

"ONWARD helped schedule echocardiogram appointments and medication deliveries. It was the easiest start to a medication we've tried yet."

—Jennifer, caregiver and parent to Aaron

Your Care Coordinator will:

- Review insurance coverage with you, keep you informed of your approval status, and offer options
- Explain what to expect, provide guidance with treatment reminders, and help find echocardiogram locations near you
- Connect with a specialty pharmacy to get your loved one's treatment
- Work with you and your healthcare provider to create a personalized plan that keeps your loved one on track

Once enrolled, you can call your Care Coordinator 7 AM to 7 PM Central Time, Monday through Friday, at <u>1-888-964-3649</u>.

Financial support for FINTEPLA

UCB is dedicated to making FINTEPLA available and affordable for every eligible patient.

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.

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.

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 <u>www.FinteplaREMS.com</u>, or call <u>1-877-964-3649</u>.

- 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:

Important Safety Information (continued)

- 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

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.

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 <u>1-888-233-2334</u> or go to <u>www.aedpregnancyregistry.org</u>. 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.

- 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



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.

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
- fast heartbeat
- nausea, vomiting, diarrhea
- high body temperature

• changes in blood pressure

trouble walking

- tight muscles
- **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

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

Important Safety Information (continued)

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

- sleepiness
- decreased appetite

• vomiting

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 <u>1-800-FDA-1088</u>.

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.



For seizures associated with Lennox-Gastaut syndrome) in patients ages 2 and older

"With fewer seizures, Aaron is enjoying more activities with passion and interest."

-Jennifer, caregiver and parent to Aaron

Aaron, living life with LGS, and his sister

Talk to a healthcare provider about FINTEPLA or get in touch with a Clinical Nurse Educator by calling 1-833-GO-DS-LGS (<u>1-833-463-7547</u>). Scan this QR code with your smartphone to add your Clinical Nurse Educator's phone number to your contacts.



Select Important Safety Information

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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.

Please see full Important Safety Information on FINTEPLA on pages 14-17 and full <u>Prescribing Information</u>, including <u>Medication Guide</u>.

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