

# Prescriber Training

**FINTEPLA® (fenfluramine) oral solution, CIV  
Risk Evaluation and Mitigation Strategy (REMS)**

# Welcome to the FINTEPLA REMS Prescriber Training

- To prescribe FINTEPLA, you must become certified in the FINTEPLA REMS, which includes reviewing this training
- After reviewing this training, you must complete and submit a **Prescriber Knowledge Assessment** and a **Prescriber Enrollment Form** before you can prescribe FINTEPLA. You can submit these:
  - **Online** at [www.FinteplaREMS.com](http://www.FinteplaREMS.com)
  - **Via fax** (1-833-568-6198)
  - **By mail** (1710 N Shelby Oaks Dr, Ste 3, Memphis, TN 38134)

**For more information or to obtain any REMS materials, visit [www.FinteplaREMS.com](http://www.FinteplaREMS.com).**

# FINTEPLA Overview

A decorative graphic consisting of two overlapping, wavy, horizontal bands. The top band is a medium purple color, and the bottom band is a light blue color. Both bands have a smooth, undulating edge, creating a sense of movement across the page.

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# What Is FINTEPLA?

FINTEPLA (fenfluramine) is indicated for the treatment of seizures associated with Dravet syndrome in patients who are 2 years of age and older.

# Risk of Valvular Heart Disease and Pulmonary Arterial Hypertension

It is important to be aware of the serious risk of valvular heart disease and pulmonary arterial hypertension associated with FINTEPLA (see **Prescribing Information** for details).

- There is an association between serotonergic drugs with 5-HT<sub>2B</sub> receptor agonist activity, including fenfluramine (the active ingredient in FINTEPLA), and valvular heart disease and pulmonary arterial hypertension
- In clinical trials of FINTEPLA for the treatment of Dravet syndrome, no cases of valvular heart disease or pulmonary hypertension were reported. Across clinical trials of FINTEPLA for the treatment of Dravet syndrome, 0.4-16% of patients taking FINTEPLA were found to have trace aortic or mitral regurgitation compared with 0-6% of patients taking placebo. Trace aortic or mitral regurgitation is considered a physiologic or normal finding in the absence of valvular abnormalities

# FINTEPLA REMS Overview

A decorative graphic consisting of two overlapping, wavy, horizontal bands. The top band is a medium purple color, and the bottom band is a light blue color. Both bands have a smooth, undulating edge, creating a fluid, wave-like appearance that spans across the width of the slide.

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# What Is the FINTEPLA REMS?

- The FINTEPLA REMS (**R**isk **E**valuation and **M**itigation **S**trategy) is a safety program to manage the serious risks of FINTEPLA
  - The FINTEPLA REMS is required by the Food and Drug Administration (FDA) because of the serious risk of valvular heart disease and pulmonary arterial hypertension
- Only prescribers and pharmacies certified by the FINTEPLA REMS can prescribe and dispense FINTEPLA to patients
  - Patients must be enrolled in the FINTEPLA REMS patient registry and follow all the safety rules in the REMS to receive FINTEPLA

# What Do I Need to Do Before Prescribing FINTEPLA?

**To prescribe FINTEPLA, you must become certified in the FINTEPLA REMS.**

Complete the following 4 steps to become certified:

- **STEP 1:** Review the FINTEPLA **Prescribing Information**
- **STEP 2:** Review the **REMS Program Overview** and the **Prescriber Training** (this document)
- **STEP 3:** Complete and submit the **Prescriber Knowledge Assessment** to the FINTEPLA REMS
- **STEP 4:** Complete and submit the **Prescriber Enrollment Form** to the FINTEPLA REMS



# What Do I Need to Do Prior to Initiating FINTEPLA?

**To receive FINTEPLA, patients must be counseled and enrolled in the FINTEPLA REMS.**

Prior to initiating treatment, using the **Patient Guide**, counsel patients on:

- The serious risk of valvular heart disease and pulmonary arterial hypertension, including how to recognize and respond to signs and symptoms of valvular heart disease and pulmonary arterial hypertension
- Cardiac monitoring via echocardiogram prior to and during treatment with FINTEPLA
- Immediately reporting any signs and symptoms of valvular heart disease and pulmonary arterial hypertension during therapy, including shortness of breath, rapid heartbeat, fatigue, chest pressure or pain, swelling of the ankles and feet, and dizziness or fainting

# What Do I Need to Do Prior to Initiating FINTEPLA? (cont)

Prior to initiating treatment:

- Enroll the patient into the FINTEPLA REMS and patient registry by completing and submitting the **Patient Enrollment Form** to the REMS
- Provide the **Patient Guide** to educate and communicate these messages with each new or refill FINTEPLA prescription
- Assess the patient by obtaining the results of the patient's baseline echocardiogram
  - Completion of patient monitoring via echocardiogram is important for early detection of valvular heart disease and pulmonary arterial hypertension
- Submit the completed **Patient Status Form** to the FINTEPLA REMS

# How Will My Patient Get FINTEPLA?

- FINTEPLA will be dispensed only by certified pharmacies
- Enrolled patients will be contacted by a certified pharmacy to set up shipment of FINTEPLA

# Echocardiographic Monitoring During Treatment

- Regular cardiac monitoring via echocardiogram can identify evidence of valvular heart disease or pulmonary arterial hypertension prior to a patient becoming symptomatic
- Monitor for valvular heart disease as indicated by mild or greater aortic regurgitation or moderate or greater mitral regurgitation
- Monitor for pulmonary arterial hypertension as indicated by elevated right heart/ pulmonary artery pressure (pulmonary arterial systolic pressure >35 mm Hg)

## Echocardiogram Monitoring Schedule



# Patient Status Form

**During treatment, prescribers must complete and submit a **Patient Status Form** to the REMS by:**

- **Assessing the patient's cardiovascular status by reporting regurgitation in the aortic and mitral valves, pulmonary arterial systolic pressure >35 mm Hg, or any new valvular abnormality as reported in the echocardiogram**

**The Patient Status Form must be completed and submitted:**

Before the start of FINTEPLA treatment

Every 6 months with the completion of each echocardiogram

3 to 6 months after treatment discontinuation with the completion of the final echocardiogram

If valvular heart disease and/or pulmonary arterial hypertension is observed on an echocardiogram, the benefits versus the risks of initiating or continuing treatment with FINTEPLA should be considered.

# Cardiovascular Adverse Events Reporting Form

**During treatment, if findings consistent with vascular heart disease, pulmonary arterial hypertension, or any new abnormality have been reported on the Patient Status Form, FINTEPLA REMS will send a follow-up Cardiovascular Adverse Event Reporting Form to obtain all required data related to the adverse event that must be completed and returned to the FINTEPLA REMS within 3 business days of receipt.**

- Valvular heart disease is indicated by mild or greater aortic regurgitation or moderate or greater mitral regurgitation
- Pulmonary arterial hypertension is indicated by elevated right heart/pulmonary artery pressure (pulmonary arterial systolic pressure >35 mm Hg)



**This concludes the Prescriber Training.**