


Fintepla[®]
(fenfluramine)
2.2 mg/mL oral solution

Prescriber Training

FINTEPLA[®] (fenfluramine) oral solution
Risk Evaluation and Mitigation Strategy (REMS)



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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
 - **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.

FINTEPLA Overview

FINTEPLA® (fenfluramine) oral solution

Risk Evaluation and Mitigation Strategy (REMS)

What Is FINTEPLA?

FINTEPLA (fenfluramine) is indicated for the treatment of seizures associated with Dravet syndrome and Lennox-Gastaut syndrome (LGS) 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_{2B} 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 and LGS, no patient developed echocardiographic findings consistent with either valvular heart disease or pulmonary arterial hypertension in the placebo-controlled studies or during the open-label extension study of up to 3 years in duration

FINTEPLA REMS Overview

FINTEPLA® (fenfluramine) oral solution

Risk Evaluation and Mitigation Strategy (REMS)

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 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 any valvular abnormality or new abnormality via echocardiogram
- Monitor for valvular heart disease as indicated by mild or greater aortic regurgitation or moderate or greater mitral regurgitation, with additional characteristics of valvular heart disease (eg, valve thickening or restrictive valve motion)
- 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

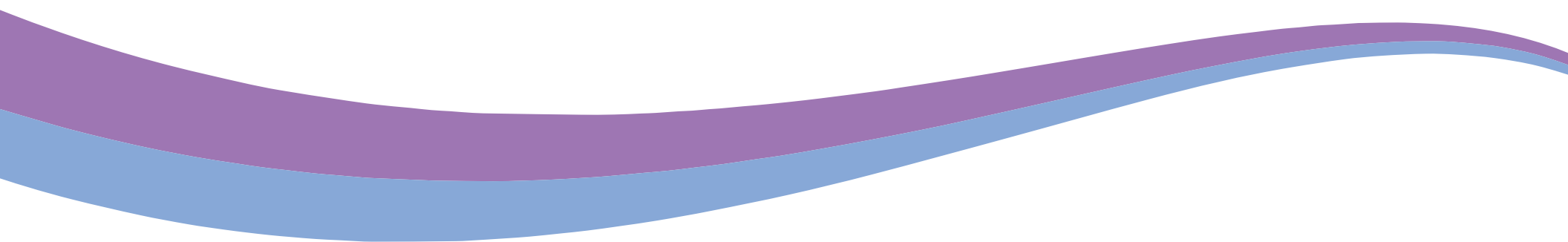
If valvular heart disease and/or pulmonary arterial hypertension is observed on an echocardiogram, the benefits versus the risks of initiating or continuing treatment with FINTEPLA should be considered.

Cardiovascular Adverse Events Reporting Form

During treatment, if findings consistent with valvular 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.

- Any valvular abnormality or new abnormality via echocardiogram
- Valvular heart disease is indicated by mild or greater aortic regurgitation or moderate or greater mitral regurgitation, with additional characteristics of valvular heart disease (eg, valve thickening or restrictive valve motion)
- Pulmonary arterial hypertension is indicated by elevated right heart/pulmonary artery pressure (pulmonary arterial systolic pressure >35 mm Hg)

This concludes the Prescriber Training.



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