



1710 N Shelby Oaks Drive, Suite 3
Memphis, TN 38134
Tel 1-877-964-3649
Fax 1-833-568-6198

[Month/Day/Year]

FINTEPLA

FDA-REQUIRED REMS SAFETY INFORMATION

Subject:

- **Risk of regurgitant valvular heart disease and/or pulmonary arterial hypertension**
- **Need for patient echocardiogram (ECHO) monitoring to mitigate the risk**

Dear Healthcare Provider:

The purpose of this letter is to inform you about the risk of FINTEPLA and the requirements of the FINTEPLA REMS. The US Food and Drug Administration (FDA) has determined that a Risk Evaluation and Mitigation Strategy (REMS) is necessary to ensure that the benefits of FINTEPLA outweigh its risks.

FINTEPLA is indicated for the treatment of seizures associated with Dravet syndrome in patients 2 years of age and older. Because of the risk of valvular heart disease and pulmonary arterial hypertension associated with FINTEPLA, patients must be monitored with an echocardiogram (ECHO). An echocardiogram can identify evidence of valvular heart disease or pulmonary arterial hypertension prior to a patient becoming symptomatic.

Counsel Your Patient

Counsel your patient on the following risks and requirements of the FINTEPLA REMS. Provide your patient with the **Patient Guide** (available at www.FinteplaREMS.com):

- Patients treated with FINTEPLA are at risk for valvular heart disease and pulmonary arterial hypertension
- Patients must be monitored by a healthcare provider for these risks and have baseline and periodic cardiac monitoring via echocardiogram every 6 months

Adverse Event Reporting

To report adverse events, contact Zogenix, Inc. at 1-866-964-3649, or the FDA at 1-800-FDA-1088 (www.fda.gov/medwatch).

For more information regarding the FINTEPLA REMS, please visit www.FinteplaREMS.com or call 1-877-964-3649.

Sincerely,

[Company Representative]

Enclosures: FINTEPLA Prescribing Information, *Prescriber Training*, and *REMS Program Overview*



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