Patient/Caregiver Guide

Patients/Caregivers:
Your healthcare provider will go over this Patient Guide with you. It is important that you ask any questions you may have. Keep this guide for important safety information about FINTEPLA.

Healthcare Providers:
Review this Patient Guide with your patients and/or their caregivers prior to initiating treatment with FINTEPLA. Give each of them a copy to take home.
What is FINTEPLA?

FINTEPLA® (fenfluramine) oral solution, CIV, is a medicine used to treat seizures in people with Dravet syndrome who are 2 years of age and older.

What is the most serious risk of FINTEPLA?

Some adults who took medicines like FINTEPLA developed problems with their heart valves or high blood pressure in the arteries of their lungs. Your healthcare provider will check your heart valves and lung artery pressures with a test called an echocardiogram (ECHO), which is an ultrasound picture of the heart. If your ECHO shows any problems with your heart valves or increased pressures in the lung arteries, your healthcare provider may tell you to stop taking FINTEPLA.

Tell your healthcare provider right away if you are having any of these signs or symptoms:
- Shortness of breath
- Rapid heartbeat
- Fatigue
- Chest pressure or pain
- Swelling of ankles and feet
- Dizziness or fainting spell

What is the FINTEPLA REMS?

A Risk Evaluation and Mitigation Strategy (REMS) is a drug safety program that the US Food and Drug Administration (FDA) can require 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. FDA must approve these steps as part of the REMS.

Why does FINTEPLA have a REMS?

FINTEPLA has a REMS because of the risk of developing problems with the heart valves and high blood pressure in the arteries of the lungs. You must be enrolled in the REMS to get FINTEPLA.

What do I need to do to enroll in the FINTEPLA REMS?

- Review this Patient Guide
- Talk to your healthcare provider about the information in this Patient Guide
- Complete the Patient Enrollment Form. Your healthcare provider will help you with this
- Get an ECHO before you start taking FINTEPLA. The ECHO will check for signs of heart valve problems or high blood pressure in the arteries of the lungs
- An ECHO can identify heart valve problems or high blood pressure in the arteries of the lungs before having any symptoms, which may help prevent serious medical problems. Therefore, it is very important to get an ECHO prior to taking FINTEPLA and at regular intervals while on the medicine

How do I receive FINTEPLA?

- After you and your healthcare provider have discussed your ECHO results and decided to begin or continue FINTEPLA, the REMS will notify the pharmacy of your decision and you will be contacted regarding next steps for obtaining FINTEPLA
- FINTEPLA is available only through pharmacies certified in the REMS. A certified pharmacy will ship the medicine directly to your home

What do I need to do during the time I am on FINTEPLA?

- You will have an ECHO every 6 months as long as you are taking FINTEPLA

What do I need to do if I stop taking FINTEPLA?

- If you stop taking FINTEPLA, you will have an ECHO one last time 3 to 6 months after your final dose
It is important that you read the Medication Guide that comes with your medicine for more information about FINTEPLA® (fenfluramine) oral solution, CIV. The REMS just covers the risk of heart valve problems and high blood pressure in the arteries of the lungs from the medication. The Medication Guide explains how to take FINTEPLA and has information about other serious risks and potential side effects.

Where can I find more information about the REMS?

• If you have questions about the REMS, you can visit www.FinteplaREMS.com or call the REMS at 1-877-964-3649 (7 AM to 7 PM Central Time)

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