ZOGENIX central™

Fintepla®
(fenfluramine) CIV
2.2 mg/mL oral solution

A Comprehensive Support Program for Patients, Families, and Their Medical Teams

What is ZOGENIX Central?

Zogenix Central is a comprehensive program dedicated to giving a personalized level of care and support to patients, families, and their medical teams throughout the entire FINTEPLA treatment journey. FINTEPLA is approved in the U.S. for the treatment of seizures associated with Dravet syndrome in patients 2 years of age and older.[1]

Families with Dravet syndrome face daily challenges that impact their lives; as such, treating a child with Dravet syndrome is more than helping them access the right medicine. Zogenix Central provides dedicated support to help patients start and continue on treatment, as well as provide their medical team with educational resources.

IMPORTANT SAFETY INFORMATION

BOXED WARNING: VALVULAR HEART DISEASE AND PULMONARY ARTERIAL HYPERTENSION

- **There is an association between serotonergic drugs with 5-HT2B receptor agonist activity, including fenfluramine (the active ingredient in FINTEPLA), and valvular heart disease and pulmonary arterial hypertension.**
- **Echocardiogram assessments are required before, during, and after treatment with FINTEPLA.**
- **FINTEPLA is available only through a restricted program called the FINTEPLA REMS**

CONTRAINDICATIONS

FINTEPLA is contraindicated in patients with Hypersensitivity to fenfluramine or any of the excipients in FINTEPLA and with concomitant use of, or within 14 days of, the administration of monoamine oxidase inhibitors because of an increased risk of serotonin syndrome.

Please see Important Safety Information throughout and full Prescribing Information and Medication Guide.

ZOGENIX Central is designed to:

Guide families on the process for starting FINTEPLA

Determine costs associated with FINTEPLA treatment and eligibility for financial assistance, and navigate that process with insurers

Liaise with Zogenix Central pharmacy partner, AnovoRx, to support the coordination and delivery of FINTEPLA to patients' homes

Provide support to patients and office staff to ensure the FINTEPLA REMS program requirements are being met, such as providing echocardiogram reminders

***FINTEPLA REMS PROGRAM**

The goal of the FINTEPLA Risk Evaluation and Mitigation Strategy (REMS) program is to mitigate the risk of valvular heart disease and pulmonary arterial hypertension associated with FINTEPLA, by ensuring that:

- Prescribers must be certified by enrolling in the FINTEPLA REMS program.
- Prescribers must counsel patients receiving FINTEPLA about the risk of valvular heart disease and pulmonary arterial hypertension, how to recognize signs and symptoms of valvular heart disease and pulmonary arterial hypertension, the need for baseline (pretreatment) and periodic cardiac monitoring via echocardiogram during FINTEPLA treatment, and cardiac monitoring after FINTEPLA treatment.
- Patients must enroll in the REMS program and comply with ongoing monitoring requirements.
- The pharmacy must be certified by enrolling in the REMS program and must only dispense to patients who are authorized to receive FINTEPLA.
- Wholesalers and distributers must only distribute to certified pharmacies.

Further information is available at www.FinteplaREMS.com or by telephone at **1-877-964-3649**.

IMPORTANT SAFETY INFORMATION (CONT.)

WARNINGS & PRECAUTIONS

VALVULAR HEART DISEASE AND PULMONARY ARTERIAL HYPERTENSION (SEE BOXED WARNING)

Because of the association between serotonergic drugs with 5-HT2B receptor agonist activity, including fenfluramine (the active ingredient in FINTEPLA), and valvular heart disease and pulmonary arterial hypertension, cardiac monitoring via echocardiogram is required prior to starting treatment, during treatment, and after treatment with FINTEPLA concludes. Cardiac monitoring via echocardiogram can aid in early detection of this condition. In clinical trials of up to 3 years in duration, no patient receiving FINTEPLA developed valvular heart disease or pulmonary arterial hypertension.

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How does ZOGENIX Central Work?

Once a patient is prescribed FINTEPLA, they will be assigned a dedicated Care Coordinator—a nurse trained in Dravet syndrome, FINTEPLA, and the insurance process—who will work with them throughout their treatment, so they have help during every step of their journey. The personal Care Coordinators will serve as the primary point of contact for all parties, including patients, doctors, their medical team, insurance companies, and the centralized specialty pharmacy. Care Coordinators will help patients and caregivers navigate many aspects of FINTEPLA such as finding local pediatric echocardiogram (echo) testing centers, helping to keep track of test schedules and follow-ups throughout their care journey, access to treatment and navigating insurance. Care Coordinators are available Monday-Friday, 7 AM-7 PM Central Time via the toll-free number **1-888-ZOGENIX (1-888-964-3649)**.

ZOGENIX Patient Assistance Programs

Zogenix is committed to helping patients with a prescription to FINTEPLA, receive it. This includes help with obtaining access to FINTEPLA at an affordable cost. For more information about Zogenix Central or support programs, including eligibility criteria, please call **1-888-ZOGENIX (1-888-964-3649)**.

IMPORTANT SAFETY INFORMATION (CONT.)

WARNINGS & PRECAUTIONS

Monitoring

Prior to starting treatment, patients must undergo an echocardiogram to evaluate for valvular heart disease and pulmonary arterial hypertension. Echocardiograms should be repeated every 6 months, and once at 3–6 months post-treatment with FINTEPLA.

If valvular heart disease or pulmonary arterial hypertension is observed on an echocardiogram, the prescriber must consider the benefits versus the risks of initiating or continuing treatment with FINTEPLA.

FINTEPLA REMS PROGRAM (SEE BOXED WARNING)

FINTEPLA is available only through a restricted distribution program called the FINTEPLA Risk Evaluation and Management Strategy (REMS) Program. Prescribers must be certified by enrolling in the FINTEPLA REMS. Prescribers must counsel patients receiving FINTEPLA about the risk of valvular heart disease and pulmonary arterial hypertension, how to recognize signs and symptoms of valvular heart disease and pulmonary arterial hypertension, the need for baseline (pretreatment) and periodic cardiac monitoring via echocardiogram during FINTEPLA treatment, and cardiac monitoring after FINTEPLA treatment. Patients must enroll in the FINTEPLA REMS and comply with ongoing monitoring requirements. The pharmacy must be certified by enrolling in the FINTEPLA REMS and must only dispense to patients who are authorized to receive FINTEPLA. Wholesalers and distributors must only distribute to certified pharmacies. Further information is available at www.FinteplaREMS.com or by telephone at 1-877-964-3649.

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IMPORTANT SAFETY INFORMATION (CONT.)

WARNINGS & PRECAUTIONS

DECREASED APPETITE AND DECREASED WEIGHT

FINTEPLA can cause decreases in appetite and weight. Decreases in weight appear to be dose related. Most patients resumed the expected measured increases in weight by the end of the open-label extension study. Weight should be monitored regularly during treatment with FINTEPLA and dose modifications should be considered if a decrease in weight is observed.

SOMNOLENCE, SEDATION, AND LETHARGY

FINTEPLA can cause somnolence, sedation, and lethargy. Other central nervous system (CNS) depressants, including alcohol, could potentiate these effects of FINTEPLA. Prescribers should monitor patients for somnolence and sedation and should advise patients not to drive or operate machinery until they have gained sufficient experience on FINTEPLA to gauge whether it adversely affects their ability to drive or operate machinery.

SUICIDAL BEHAVIOR AND IDEATION

Antiepileptic drugs (AEDs) increase the risk of suicidal thoughts or behaviors in patients taking these drugs for any indication. Patients treated with an AED for any indication should be monitored for the emergence or worsening of depression, suicidal thoughts or behaviors, or any unusual changes in mood or behavior.

Anyone considering prescribing FINTEPLA or any other AED must balance the risk of suicidal thoughts or behaviors with the risks of untreated illness. Epilepsy and many other illnesses for which AEDs are prescribed are themselves associated with morbidity and mortality and an increased risk of suicidal thoughts and behaviors. Should suicidal thoughts and behaviors emerge during treatment, consider whether the emergence of these symptoms in any given patient may be related to the illness being treated.

WITHDRAWAL OF ANTIEPILEPTIC DRUGS

As with most AEDs, FINTEPLA should generally be withdrawn gradually because of the risk of increased seizure frequency and status epilepticus. If withdrawal is needed because of a serious adverse reaction, rapid discontinuation can be considered.

SEROTONIN SYNDROME

Serotonin syndrome, a potentially life-threatening condition, may occur with FINTEPLA, particularly during concomitant administration of FINTEPLA with other serotonergic drugs, including, but not limited to, selective serotonin-norepinephrine reuptake inhibitors (SNRIs), selective serotonin reuptake inhibitors (SSRIs), tricyclic antidepressants (TCAs), bupropion, triptans, dietary supplements (eg, St. John's Wort, tryptophan), drugs that impair metabolism of serotonin (including monoamine oxidase inhibitors [MAOIs], which are contraindicated with FINTEPLA), dextromethorphan, lithium, tramadol, and antipsychotics with serotonergic agonist activity. Patients should be monitored for the emergence of signs and symptoms of serotonin syndrome, which include mental status changes (eg, agitation, hallucinations, coma), autonomic instability (eg, tachycardia, labile blood pressure, hyperthermia), neuromuscular signs (eg, hyperreflexia, incoordination), and/or gastrointestinal symptoms (eg, nausea, vomiting, diarrhea). If serotonin syndrome is suspected, treatment with FINTEPLA should be stopped immediately, and symptomatic treatment should be started.

IMPORTANT SAFETY INFORMATION (CONT.)

WARNINGS & PRECAUTIONS

INCREASE IN BLOOD PRESSURE

FINTEPLA can cause an increase in blood pressure. Significant elevation in blood pressure, including hypertensive crisis, has been reported rarely in adult patients treated with fenfluramine, including patients without a history of hypertension. Monitor blood pressure in patients treated with FINTEPLA. In clinical trials of up to 3 years in duration, no patient receiving FINTEPLA developed hypertensive crisis.

GLAUCOMA

Fenfluramine can cause mydriasis and can precipitate angle closure glaucoma. Consider discontinuing treatment with FINTEPLA in patients with acute decreases in visual acuity or ocular pain.

ADVERSE REACTIONS

The most common adverse reactions (incidence at least 10% and greater than placebo) were: decreased appetite; somnolence, sedation, lethargy; diarrhea; constipation; abnormal echocardiogram; fatigue, malaise, asthenia; ataxia, balance disorder, gait disturbance; blood pressure increased; drooling, salivary hypersecretion; pyrexia; upper respiratory tract infection; vomiting; decreased weight; fall; status epilepticus.

DRUG INTERACTIONS

Strong CYP1A2 and CYP2B6 Inducers: Coadministration with rifampin or a strong CYP1A2 and CYP2B6 inducer will decrease fenfluramine plasma concentrations.

Consider an increase in FINTEPLA dosage when coadministered with rifampin or a strong CYP1A2 and CYP2B6 inducer.

USE IN SPECIFIC POPULATIONS

Administration to patients with moderate or severe renal impairment or to patients with hepatic impairment is not recommended.

REFERENCES

1. Zogenix. 2020. FINTEPLA: Highlights of Prescribing Information. Emeryville, CA. Author.

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