ZOGENIX central™ | Support for Patients & Families

Zogenix Central—The Heart of an Exceptional Patient Care Experience

Zogenix Central is a comprehensive patient service program that offers caregivers personalized support, education, and resources to help them navigate the process of starting and staying on FINTEPLA® (fenfluramine) oral solution, CIV.

Zogenix Central's patient-focused model of care offers every family and their healthcare provider their very own Care Coordinator—a nurse trained in Dravet syndrome and FINTEPLA—who will remain constant throughout their entire FINTEPLA treatment journey.

For caregivers: Care Coordinators provide personalized support by:

- ✓ Helping navigate the insurance process and determining if the patient is eligible for financial assistance
- ✓ Identifying local centers that conduct pediatric echocardiograms, providing reminders and support in scheduling these tests
- ✓ Proactively reaching out regarding prescription refills to ensure that there are no missed doses
- ✓ Coordinating with the Zogenix Central pharmacy partner, AnovoRx, regarding medication shipments

In addition, caregivers have 24/7/365 access to a dedicated Zogenix Central pharmacy team trained in Dravet syndrome and FINTEPLA.

For healthcare providers: Care Coordinators provide support by:

- ✓ Answering questions and providing updates on patients getting started on FINTEPLA
- ✓ Facilitating benefits verification, prior authorizations, and appeals
- ✓ Dealing with issues and finding solutions to potential obstacles
- ✓ Checking that the FINTEPLA REMS requirements are being met, such as by sending echocardiogram reminders
- ✓ Providing tools and resources for caregiver education

FINTEPLA financial assistance

Zogenix is committed to making FINTEPLA affordable and accessible for patients through a number of financial assistance programs, including:

- ✓ The Zogenix Patient Support Program may be able to help families and patients who are uninsured get access to FINTEPLA
- ✓ The Zogenix Copay Support Program is designed to help families and patients who have commercial health insurance to afford the costs of treatment with FINTEPLA. This may include help with costs associated with copayments, deductibles, and/or coinsurance
- ✓ The Zogenix Echocardiogram Copay Support Program is designed to help eligible families who are self insured, or insured by their employer, with the costs associated with echocardiograms, such as copayments, deductibles, and/or coinsurance

Through the Zogenix Patient Support Program, families can pay as little as $0 copay costs for FINTEPLA and associated echocardiograms. Zogenix is committed that no family will pay any more than $25 in out-of-pocket copays for FINTEPLA. See eligibility* requirements below.

$0

For more information about Zogenix Central or financial assistance, including eligibility criteria, call 1-888-ZOGENIX (1-888-964-3649).

Abbreviated Terms and Conditions

*Patient must have a FINTEPLA prescription from a licensed prescriber, and be a resident of the United States or the Commonwealth of Puerto Rico, with a valid mailing address (no PO boxes). The Copay Assistance Program is not health insurance and is not valid for prescriptions that are eligible to be reimbursed, in whole or in part, by Medicaid, Medicare, or other government healthcare programs. Certain state restrictions may apply. Zogenix reserves the right to change or discontinue this offer without notice. Please see full terms and conditions.

Please see Important Safety Information on next page and full Prescribing Information, including Boxed Warning.

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

INDICATIONS AND USAGE

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

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.

WARNINGS AND 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.

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 Mitigation 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.

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.

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.

Please see full Prescribing Information, including Boxed Warning, for additional important information on FINTEPLA.

To learn more about FINTEPLA and have a Zogenix Key Account Manager contact you, visit FinteplaHCP.com.

ZOGENIX