



A NEW WAY FORWARD

Helping you help them. It's that simple.

ONWARD is your go-to program designed to support staff and patients throughout the treatment experience. We know efficiency means everything to your practice, and that's why we provide:

- **Dedicated Field Specialists**
- **Easily accessible tools and resources**
- **The ONWARD Provider Portal**

INDICATIONS AND USAGE

FINTEPLA is indicated for the treatment of seizures associated with Dravet syndrome (DS) and Lennox-Gastaut syndrome (LGS) 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-HT_{2B} 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, or within 14 days of the administration of monoamine oxidase inhibitors because of an increased risk of serotonin syndrome.

Please see additional Important Safety Information on the back and accompanying full Prescribing Information, including Boxed Warning.


Fintepla®
(fenfluramine)
2.2 mg/mL oral solution

PERSONALIZED SUPPORT
FOR YOU +
YOUR TEAM

PERSONALIZED SUPPORT
FOR YOUR
PATIENTS



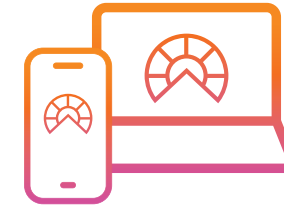
Dedicated Field Specialists can save you valuable time

From the start of treatment to ongoing administrative needs, they provide:

- **A single point of contact** between your office and ONWARD support
- **Operational expertise** in ONWARD capabilities and REMS processes
- **Communications with your office** on prescription authorizations and appeal requirements via preferred channels (live, phone, fax, Provider Portal)

One-on-one resources for your patients and their families

- **Clinical Nurse Educators (CNEs)** answer questions and provide treatment education for patients and families prior to starting treatment
- **Care Coordinators** support patients and families from time of referral submission to provide appointment reminders, facilitate treatment refills, and more



A central place for what you need, when you need it

The Provider Portal offers easy access to key online tools and resources:

- **Patient referrals:** See a list of all referred patients and forms pending signatures
- **Echocardiogram monitoring:** Track Patient Status Form due dates

The ONWARD team will provide notifications letting you know that action is required to support a patient

Ready to get started?

Create a login to the provider portal using either option below, then log in to enroll a patient

- Provide all of the necessary information on the Portal User Enrollment Form and add electronic signature via DocuSign
- Download and print the Portal User Enrollment Form, complete and sign the form, and submit to www.ONWARDProviderPortal.com

Have questions?

Make an appointment with a Field Specialist at 1-888-964-3649 or contact your UCB representative to learn more

Features at your fingertips



Locate echocardiography facility: Find an adult or pediatric echocardiogram facility near you and your patients



Exchange patient-specific information: Send and receive secure messages



Request a call: Your UCB representative is available to provide additional information



Link to CoverMyMeds: A resource that helps with access solutions



Upload a document: Share relevant materials that help build out patient profiles



ONWARD™

Taking support to the next level

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Valvular Heart Disease and Pulmonary Arterial Hypertension: Because of the association between serotonergic drugs with 5-HT_{2B} receptor agonist activity, including fenfluramine (the active ingredient in FINTEPLA), and valvular heart disease (VHD) and pulmonary arterial hypertension (PAH), 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 these conditions. In clinical trials for DS and LGS of up to 3 years in duration, no patient receiving FINTEPLA developed VHD or PAH.

Monitoring: Prior to starting treatment, patients must undergo an echocardiogram to evaluate for VHD and PAH. Echocardiograms should be repeated every 6 months, and once at 3-6 months post treatment with FINTEPLA.

The prescriber must consider the benefits versus the risks of initiating or continuing treatment with FINTEPLA if any of the following signs are observed via echocardiogram: valvular abnormality or new abnormality; VHD indicated by mild or greater aortic regurgitation or moderate or greater mitral regurgitation, with additional characteristics of VHD (eg, valve thickening or restrictive valve motion); PAH indicated by elevated right heart/pulmonary artery pressure (PASP >35 mm Hg).

FINTEPLA REMS Program: 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, the need for baseline (pretreatment) and periodic cardiac monitoring via echocardiogram during treatment, and cardiac monitoring after 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. Weight should be monitored regularly, and dose modifications should be considered if weight decreases.

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), including FINTEPLA, increase the risk of suicidal thoughts or behaviors in patients. Patients treated with an AED 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 must balance the risk of suicidal thoughts or behaviors with the risks of untreated illness. Epilepsy is associated with morbidity and mortality and an increased risk of suicidal thoughts and behaviors.

Withdrawal of Antiepileptic Drugs: FINTEPLA should 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. Rare cases of significant elevation in blood pressure, including hypertensive crisis, have been reported in adult patients treated with fenfluramine, including patients without a history of hypertension. In clinical trials for DS and LGS of up to 3 years in duration, no pediatric or adult patient receiving FINTEPLA developed hypertensive crisis. Monitor blood pressure in patients treated with FINTEPLA.

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 observed in DS studies 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.

The most common adverse reactions observed in the LGS study were diarrhea; decreased appetite; fatigue; somnolence; vomiting.

To report SUSPECTED ADVERSE REACTIONS, contact UCB, Inc. at 1-844-599-2273 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see accompanying full Prescribing Information, including Boxed Warning, for additional Important Safety Information on FINTEPLA.