RISK EVALUATION AND MITIGATION STRATEGY (REMS) Document
FINTEPLA (fenfluramine) REMS Program

I. Administrative Information

Application Number: NDA 212102

Application Holder: Zogenix, Inc.

Initial REMS Approval: 06/2020

II. REMS Goals

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:

1. Ensuring prescribers are educated on:
   a. The risk of valvular heart disease and pulmonary arterial hypertension associated with FINTEPLA.
   b. The need to counsel patients on how to recognize and respond to signs and symptoms of valvular heart disease and pulmonary arterial hypertension.
   c. The need to enroll patients in the FINTEPLA REMS.
   d. The need to submit documentation of baseline and periodic cardiac monitoring of patients to identify valvular heart disease and pulmonary arterial hypertension.
2. Ensuring prescribers adhere to the following:
   a. Enroll patients in the FINTEPLA REMS.
   b. Submit documentation of baseline cardiac monitoring.
   c. Submit documentation of periodic cardiac monitoring.
3. Ensuring patients are educated on the following:
   a. How to recognize and respond to signs and symptoms of valvular heart disease and pulmonary arterial hypertension.
   b. The need to have baseline and periodic cardiac monitoring.
4. Enrolling of all patients in a registry to further support the long-term safety and safe use of FINTEPLA.

III. REMS Requirements

Zogenix, Inc. must ensure that healthcare providers, patients, pharmacies, and wholesaler-distributors comply with the following requirements:

1. Healthcare providers who prescribe FINTEPLA must:	
To become certified to prescribe	1. Review the drug's Prescribing Information. 2. Review the following: Prescriber Training and REMS Program Overview. 3. Successfully complete the Prescriber Knowledge Assessment and submit it to the REMS Program. 4. Enroll in the REMS by completing the Prescriber Enrollment Form and submitting it to the REMS Program.

1. **Healthcare providers who prescribe FINTEPLA must:**	
Before treatment initiation (first dose)	5. Counsel the patient on the risks of valvular heart disease and pulmonary arterial hypertension, including how to recognize and respond to signs and symptoms of valvular heart disease and pulmonary arterial hypertension, and the need for cardiac monitoring via echocardiogram at baseline (treatment initiation), every 6 months during treatment, and once 3 to 6 months after treatment discontinuation using the Patient Guide. 6. Provide the patient with the Patient Guide. 7. Enroll the patient by completing and submitting the Patient Enrollment Form to the REMS. 8. Assess the patient's cardiovascular status and the appropriateness of initiating treatment by obtaining an echocardiogram. Document and submit the results and authorization for treatment to the REMS Program using the Patient Status Form.
During treatment: Every 6 months	9. Counsel the patient on the need for cardiac monitoring via echocardiogram every 6 months during treatment using the Patient Guide. 10. Assess the patient's cardiovascular status and the appropriateness of continuing treatment by obtaining an echocardiogram. Document and submit the results and appropriateness of continued treatment to the REMS Program using the Patient Status Form.
After treatment discontinuation: 3 to 6 months	11. Assess the patient's cardiovascular status by obtaining an echocardiogram. Document and submit the results to the REMS Program using the Patient Status Form.
At all times	12. Report adverse events suggestive of valvular heart disease and/or pulmonary arterial hypertension on the Cardiovascular Adverse Event Reporting Form to the REMS Program. 13. Report treatment discontinuation or transfer of care to the REMS Program.

2. **Patients who are prescribed FINTEPLA:**	
Before treatment initiation	1. Review the Patient Guide. 2. Enroll in the REMS by completing the Patient Enrollment Form with the prescriber. Enrollment information will be provided to the REMS Program. 3. Receive counseling from the prescriber on the risk of valvular heart disease and pulmonary arterial hypertension, including how to recognize signs and symptoms of valvular heart disease and pulmonary arterial hypertension, and the need to get an echocardiogram before treatment, every 6 months during treatment, and once 3 to 6 months after treatment discontinuation using the Patient Guide. 4. Get an echocardiogram to check your heart.

2. Patients who are prescribed FINTEPLA:	
During treatment: Every 6 months	5. Receive counseling from the prescriber on the need to get an echocardiogram every 6 months during treatment using the Patient Guide. 6. Get an echocardiogram to check your heart.
After treatment discontinuation: 3 to 6 months	7. Get an echocardiogram to check your heart.
At all times	8. Inform the prescriber if any signs or symptoms of valvular heart disease or pulmonary arterial hypertension develop. 9. Inform all healthcare providers about this treatment.

3. Outpatient pharmacies that dispense FINTEPLA must:	
To become certified to dispense	1. Designate an authorized representative to carry out the certification process and oversee implementation and compliance with the REMS Program on behalf of the pharmacy. 2. Have the authorized representative review the Pharmacy Guide and REMS Program Overview. 3. Have the authorized representative enroll in the REMS Program by completing the Outpatient Pharmacy Enrollment Form and submitting it to the REMS. 4. Train all relevant staff involved in dispensing FINTEPLA on the REMS requirements using the Pharmacy Guide.
Before dispensing	5. Obtain authorization to dispense by contacting the REMS Program to verify that the prescriber is certified, and the patient is enrolled and authorized to receive the drug.
To maintain certification to dispense	6. Have the new authorized representative enroll in the REMS Program by completing the Outpatient Pharmacy Enrollment Form if the authorized representative changes.
At all times	7. Not distribute, transfer, loan, or sell FINTEPLA, except to certified pharmacies. 8. Maintain records of dispensing information. 9. Maintain records that all processes and procedures are in place and being followed. 10. Maintain records documenting staff's completion of REMS training. 11. Comply with audits carried out by Zogenix, Inc. or a third party acting on behalf of Zogenix, Inc. to ensure that all processes and procedures are in place and are being followed.

4. Inpatient pharmacies that dispense FINTEPLA must:	
To become certified to dispense	1. Designate an authorized representative to carry out the certification process and oversee implementation and compliance with the REMS on behalf of the pharmacy. 2. Have the authorized representative review the Pharmacy Guide and REMS Program Overview.

4. Inpatient pharmacies that dispense FINTEPLA must:	
	3. Have the authorized representative enroll in the REMS by completing the Inpatient Pharmacy Enrollment Form and submitting it to the REMS. 4. Train all relevant staff involved in dispensing FINTEPLA on the REMS Program requirements using the Pharmacy Guide.
Before dispensing	5. For patients initiating treatment: Obtain authorization to dispense each prescription by contacting the REMS Program to verify that the prescriber is certified, and the patient is enrolled and authorized to receive the drug. 6. For patients continuing treatment: Obtain authorization to dispense each prescription by contacting the REMS Program to verify that the patient is enrolled and authorized to receive the drug.
At discharge	7. Dispense no more than 15 days' supply
To maintain certification to dispense	8. Have the new authorized representative enroll in the REMS Program by completing the Inpatient Pharmacy Enrollment Form if the authorized representative changes.
At all times	9. Not distribute, transfer, loan, or sell FINTEPLA 10. Maintain records of dispensing information. 11. Maintain records that all processes and procedures are in place and being followed. 12. Maintain records that document staff's completion of REMS training. 13. Comply with audits carried out by Zogenix, Inc. or a third party acting on behalf of Zogenix, Inc. to ensure that all processes and procedures are in place and are being followed.

5. Wholesale-distributors that distribute FINTEPLA must:	
To be able to distribute	1. Establish processes and procedures to ensure that the drug is distributed only to certified pharmacies. 2. Train all relevant staff involved in distributing FINTEPLA on the REMS requirements.
At all times	3. Distribute FINTEPLA only to certified pharmacies. 4. Maintain records of all distributions. 5. Comply with audits carried out by Zogenix, Inc. or a third party acting on behalf of Zogenix, Inc. to ensure that all processes and procedures are in place and are being followed.

Zogenix, Inc. must provide training to healthcare providers who prescribe FINTEPLA.

The training includes the following educational materials: Prescriber Training, REMS Program Overview, and Prescriber Knowledge Assessment. The training must be available online and in hard-copy format via fax and mail.

Zogenix, Inc. must provide training to pharmacies that dispense FINTEPLA.

The training includes the following educational materials: Pharmacy Guide and REMS Program Overview. The training must be available online and in hard-copy format via fax and mail.

To inform healthcare providers about the REMS and the risks and safe use of FINTEPLA, Zogenix, Inc. must disseminate REMS communication materials according to the table below:

Target Audience	Communication Materials and Dissemination Plans
Healthcare providers who are likely to prescribe FINTEPLA	REMS Letter: Letter for Healthcare Providers, with attachments: Prescribing Information, Prescriber Training, and REMS Program Overview 1. Email within 60 calendar days of the date FINTEPLA is first commercially distributed and again 6 months later. a. Send by mail within 30 calendar days of the date of the first email if the healthcare provider's email address is not available or the email is undeliverable. b. Send a second email within 30 calendar days of the date the first email was sent if the first email is marked as unopened. c. Send by mail within 30 calendar days of the date the second email was sent if the second email is marked as unopened. 2. Disseminate through field-based sales representatives and medical science liaisons during initial/follow-up discussion with healthcare providers for 12 months from the date FINTEPLA is first commercially distributed. 3. Disseminate through the following professional societies and request the letter or content be provided to their members. a. American Epilepsy Society; Child Neurology Society; American Academy of Neurology. 4. Disseminate and prominently display at professional meetings where Zogenix, Inc. has a presence for 12 months from the date FINTEPLA is first commercially distributed.

To support REMS Program operations, Zogenix, Inc. must:

1. Authorize dispensing for each patient based on receipt of the Patient Status Form on the following schedule: prior to initiation of treatment, and for subsequent dispensing, within 270 calendar days from the date of receipt of the last Patient Status Form. If a complete Patient Status Form is not received within 270 calendar days, the patient is not authorized to receive the drug until a completed form is received.
2. Establish and maintain a REMS Program website, www.FinteplaREMS.com. The REMS Program website must include the capability to complete prescriber certification, pharmacy certification, and enroll and manage patients online, to obtain authorization to dispense online, and the option to print the Prescribing Information, Medication Guide, and REMS materials. All product websites for consumers and healthcare providers must include REMS-specific prominent links to the REMS Program website. The REMS Program website must not link back to any promotional product websites.
3. Make the REMS Program website fully operational and make all REMS materials available through the REMS Program website and call center by the date FINTEPLA is first commercially distributed.
4. Establish and maintain a REMS Program call center for REMS participants at 1-877-964-3649.
5. Establish and maintain a validated, secure database of all REMS participants who are enrolled and/or certified in the FINTEPLA REMS Program.
6. Ensure prescribers are able to complete the certification process online, by fax and mail.

7. Ensure prescribers are able to enroll their patients in the REMS online, by fax and mail.
8. Ensure pharmacies are able to complete the certification process online, by fax and mail.
9. Ensure prescribers are able to submit the Patient Status Form to the REMS online, by fax, and by mail.
10. Ensure prescribers are able to report adverse events suggestive of valvular heart disease and pulmonary arterial hypertension via the Patient Status Form online, by fax, and by mail.
11. Ensure pharmacies are able to obtain authorization to dispense online and by phone.
12. Provide the Prescriber Training, REMS Program Overview, Prescriber Enrollment Form, Patient Enrollment Form, and Prescribing Information to healthcare providers who (1) attempt to prescribe FINTEPLA and are not yet certified or (2) inquire about how to become certified.
13. Provide the Pharmacy Guide, REMS Program Overview, and Inpatient Pharmacy Enrollment Form or Outpatient Pharmacy Enrollment Form, as appropriate, to pharmacies that (1) attempt to dispense FINTEPLA and are not yet certified or (2) inquire about how to become certified.
14. Notify prescribers, patients, and pharmacies within 2 business days after they become enrolled and/or certified in the REMS Program.
15. Provide certified prescribers access to the database of certified pharmacies and enrolled patients.
16. Provide certified pharmacies access to the database of certified prescribers and enrolled patients.
17. Provide authorized wholesale-distributors access to the database of certified pharmacies.
18. Establish and maintain a registry for all patients that includes a reporting and collection system for all patients to provide information on patient outcomes and the incidence of valvular heart disease and pulmonary arterial hypertension.
19. Ensure that, once a report suggestive of valvular heart disease or pulmonary arterial hypertension is received, Zogenix, Inc. follows up with the healthcare provider(s) to complete a Cardiovascular Adverse Event Reporting Form, to obtain all required data related to the adverse event for the registry.

To ensure REMS participants' compliance with the REMS Program, Zogenix, Inc. must:

20. Ensure the Patient Status Form is received for each patient on the following schedule: For treatment initiation, the patient is not authorized to receive the drug until the form is received. For subsequent dispensing, if the Patient Status Form is not received within 180 calendar days of the date of receipt of the last Patient Status Form, Zogenix, Inc. must contact the prescriber to obtain the form. If the form is not received within 270 calendar days, the patient is not authorized to receive the drug until the form is received.
21. Verify annually that the authorized representative's name and contact information corresponds to those of the current designated authorized representative for the pharmacy. If different, the pharmacy must be required to re-certify with a new authorized representative.
22. Maintain adequate records to demonstrate that REMS requirements have been met, including, but not limited to, records of FINTEPLA distribution and dispensing; certification of prescribers and pharmacies; enrollment and status of patients; documentation of completed Patient Status Forms and Cardiovascular Adverse Event Reporting Form; and audits of REMS participants. These records must be readily available for FDA inspections.
23. Establish a plan for addressing noncompliance with REMS requirements.
24. Monitor prescribers, pharmacies, and wholesale-distributors on an ongoing basis to ensure the REMS requirements are being met. Take corrective action if noncompliance is identified, including decertification.
25. Audit pharmacies and wholesale-distributors no later than 90 calendar days after they become certified and have received at least one shipment, and annually thereafter, to ensure that REMS processes and procedures are in place, functioning, and support the REMS requirements.
26. Take reasonable steps to improve implementation of and compliance with the REMS requirements based on monitoring and evaluation of the FINTEPLA REMS.

IV. REMS Assessment Timetable

Zogenix, Inc. must submit REMS assessments at 6 months and 12 months from the date of the initial approval of the REMS and annually thereafter. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 calendar days before the submission date for that assessment. Zogenix, Inc. must submit each assessment so that it will be received by the FDA on or before the due date.

V. REMS Materials

The following materials are part of the FINTEPLA REMS:

Enrollment Forms

Prescriber:

1. Prescriber Enrollment Form

Patient:

2. Patient Enrollment Form

Pharmacy:

3. Outpatient Pharmacy Enrollment Form
4. Inpatient Pharmacy Enrollment Form

Training and Educational Materials

Prescriber:

5. Prescriber Training
6. REMS Program Overview
7. Prescriber Knowledge Assessment

Patient:

8. Patient Guide

Pharmacy:

9. Pharmacy Guide
10. REMS Program Overview

Patient Care Forms

11. Patient Status Form
12. Cardiovascular Adverse Event Reporting Form

Communication Materials

13. Letter for Healthcare Providers

Other Materials

14. REMS Website

PRESCRIBER INFORMATION	* indicates required field.
First Name*:	Practice/Facility Name*:

PRESCRIBER AGREEMENT

PATIENT INFORMATION

* indicates required field.

First Name*:	Phone*: Home: Work:

PRESCRIBER INFORMATION

* indicates required field.

PATIENT AGREEMENT

PRESCRIBER AGREEMENT

By signing below, I acknowledge that I have reviewed the risks of FINTEPLA and the requirements of the REMS with this patient.

STEP 1: REVIEW	STEP 2: COMPLETE AND SIGN	STEP 3: SUBMIT

OUTPATIENT PHARMACY INFORMATION

* indicates required field.

Pharmacy Name*:	Pharmacy Address Line 1*:

AUTHORIZED REPRESENTATIVE INFORMATION

* indicates required field.

First Name*:	Phone*:	Fax:

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AUTHORIZED PHARMACY REPRESENTATIVE AGREEMENT

I am the Authorized Representative designated by my Outpatient Pharmacy to coordinate the activities of the REMS.
By completing, signing, and submitting this form, on behalf of myself and my Outpatient Pharmacy, **I attest that:**

- I have reviewed the *Pharmacy Guide* and the *REMS Program Overview*
- I am enrolling in the REMS
- I agree to train all relevant staff involved in dispensing FINTEPLA on the REMS requirements using the *Pharmacy Guide*
- I will ensure that, before dispensing, all pharmacy staff obtain authorization to dispense each prescription by contacting the FINTEPLA REMS to verify that the prescriber is certified and the patient is enrolled and authorized to receive FINTEPLA
- I agree to ensure that all pharmacy staff do not distribute, transfer, loan, or sell FINTEPLA, except to certified pharmacies
- I will maintain records of dispensing information
- I will maintain records documenting staff's completion of REMS training
- I will maintain records that all REMS processes and procedures are in place and being followed
- I will ensure that all pharmacy staff comply with audits carried out by Zogenix, Inc. or a third party acting on behalf of Zogenix, Inc. to ensure that all processes and procedures are in place and are being followed
- If the authorized representative changes, this pharmacy will have the new authorized representative enroll in the REMS by completing the *Outpatient Pharmacy Enrollment Form*

STEP 1: REVIEW	STEP 2: COMPLETE AND SIGN	STEP 3: SUBMIT

INPATIENT PHARMACY INFORMATION

* indicates required field.

Pharmacy Name*:	Pharmacy Address Line 1*:

AUTHORIZED REPRESENTATIVE INFORMATION

First Name*:	Phone*:	Fax:

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AUTHORIZED PHARMACY REPRESENTATIVE AGREEMENT

I am the Authorized Representative designated by my Inpatient Pharmacy to coordinate the activities of the REMS.
By completing, signing, and submitting this form, on behalf of myself and my Inpatient Pharmacy, **I attest that:**

- I have reviewed the *Pharmacy Guide* and the *REMS Program Overview*
- I am enrolling in the REMS
- I agree to train all relevant staff involved in dispensing FINTEPLA on the REMS requirements using the *Pharmacy Guide*
- For patients initiating treatment: Before dispensing, all pharmacy staff must obtain authorization to dispense each prescription by contacting the FINTEPLA REMS to verify that the prescriber is certified, and the patient is enrolled and authorized to receive FINTEPLA
- For patients continuing treatment: Before dispensing, all pharmacy staff must obtain authorization to dispense each prescription by contacting the REMS to verify that the patient is under the care of a certified prescriber, and the patient is enrolled and authorized to receive FINTEPLA
- I will not dispense more than 15 days' supply at discharge
- I agree to ensure that all pharmacy staff do not distribute, transfer, loan, or sell FINTEPLA
- I will maintain records of dispensing information
- I will maintain records documenting staff's completion of REMS training
- I will maintain records that all REMS processes and procedures are in place and being followed
- I will ensure that all pharmacy staff comply with audits carried out by Zogenix, Inc. or a third party acting on behalf of Zogenix, Inc. to ensure that all processes and procedures are in place and are being followed
- If the authorized representative changes, this pharmacy will have the new authorized representative enroll in the REMS my completing the *Inpatient Pharmacy Enrollment Form*

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

Prescriber Training

FINTEPLA® (fenfluramine) oral solution, CIV
Risk Evaluation and Mitigation Strategy (REMS)

Welcome to the FINTEPLA REMS Prescriber Training

- To prescribe FINTEPLA, you must become certified in the FINTEPLA REMS, which includes reviewing this training

- After reviewing this training, you must complete and submit a **Prescriber Knowledge Assessment** and a **Prescriber Enrollment Form** before you can prescribe FINTEPLA. You can submit these:
  - **Online** at www.FinteplaREMS.com
  - **Via fax** (1-833-568-6198)
  - **By mail** (1710 N Shelby Oaks Dr, Ste 3, Memphis, TN 38134)

For more information or to obtain any REMS materials, visit www.FinteplaREMS.com.

FINTEPLA Overview

FINTEPLA® (fenfluramine) oral solution, CIV
Risk Evaluation and Mitigation Strategy (REMS)

What Is FINTEPLA?

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

Risk of Valvular Heart Disease and Pulmonary Arterial Hypertension

It is important to be aware of the serious risk of valvular heart disease and pulmonary arterial hypertension associated with FINTEPLA (see **Prescribing Information** for details).

- 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
- In clinical trials of FINTEPLA for the treatment of Dravet syndrome, no cases of valvular heart disease or pulmonary hypertension were reported. Across clinical trials of FINTEPLA for the treatment of Dravet syndrome, 0.4-16% of patients taking FINTEPLA were found to have trace aortic or mitral regurgitation compared with 0-6% of patients taking placebo. Trace aortic or mitral regurgitation is considered a physiologic or normal finding in the absence of valvular abnormalities

FINTEPLA REMS Overview

FINTEPLA® (fenfluramine) oral solution, CIV
Risk Evaluation and Mitigation Strategy (REMS)

What Is the FINTEPLA REMS?

- The FINTEPLA REMS (**R**isk **E**valuation and **M**itigation **S**trategy) is a safety program to manage the serious risks of FINTEPLA
- The FINTEPLA REMS is required by the Food and Drug Administration (FDA) because of the serious risk of valvular heart disease and pulmonary arterial hypertension

- Only prescribers and pharmacies certified by the FINTEPLA REMS can prescribe and dispense FINTEPLA to patients
- Patients must be enrolled in the FINTEPLA REMS patient registry and follow all the safety rules in the REMS to receive FINTEPLA

What Do I Need to Do Before Prescribing FINTEPLA?

To prescribe FINTEPLA, you must become certified in the FINTEPLA REMS.

Complete the following 4 steps to become certified:

- **STEP 1:** Review the FINTEPLA **Prescribing Information**
- **STEP 2:** Review the **REMS Program Overview** and the **Prescriber Training** (this document)
- **STEP 3:** Complete and submit the **Prescriber Knowledge Assessment** to the FINTEPLA REMS
- **STEP 4:** Complete and submit the **Prescriber Enrollment Form** to the FINTEPLA REMS

What Do I Need to Do Prior to Initiating FINTEPLA?

To receive FINTEPLA, patients must be counseled and enrolled in the FINTEPLA REMS.

Prior to initiating treatment, using the **Patient Guide**, counsel patients on:

- The serious risk of valvular heart disease and pulmonary arterial hypertension, including how to recognize and respond to signs and symptoms of valvular heart disease and pulmonary arterial hypertension
- Cardiac monitoring via echocardiogram prior to and during treatment with FINTEPLA
- Immediately reporting any signs and symptoms of valvular heart disease and pulmonary arterial hypertension during therapy, including shortness of breath, rapid heartbeat, fatigue, chest pressure or pain, swelling of the ankles and feet, and dizziness or fainting

What Do I Need to Do Prior to Initiating FINTEPLA? (cont)

Prior to initiating treatment:

- Enroll the patient into the FINTEPLA REMS and patient registry by completing and submitting the **Patient Enrollment Form** to the REMS
- Provide the **Patient Guide** to educate and communicate these messages with each new or refill FINTEPLA prescription
- Assess the patient by obtaining the results of the patient's baseline echocardiogram
  - Completion of patient monitoring via echocardiogram is important for early detection of valvular heart disease and pulmonary arterial hypertension
- Submit the completed **Patient Status Form** to the FINTEPLA REMS

How Will My Patient Get FINTEPLA?

- FINTEPLA will be dispensed only by certified pharmacies
- Enrolled patients will be contacted by a certified pharmacy to set up shipment of FINTEPLA

Echocardiographic Monitoring During Treatment

- Regular cardiac monitoring via echocardiogram can identify evidence of valvular heart disease or pulmonary arterial hypertension prior to a patient becoming symptomatic
- Monitor for valvular heart disease as indicated by mild or greater aortic regurgitation or moderate or greater mitral regurgitation
- Monitor for pulmonary arterial hypertension as indicated by elevated right heart/ pulmonary artery pressure (pulmonary arterial systolic pressure >35 mm Hg)

Echocardiogram Monitoring Schedule

Patient Status Form

During treatment, prescribers must complete and submit a Patient Status Form to the REMS by:

- **Assessing the patient's cardiovascular status by reporting regurgitation in the aortic and mitral valves, pulmonary arterial systolic pressure >35 mm Hg, or any new valvular abnormality as reported in the echocardiogram**

The Patient Status Form must be completed and submitted:

- Before the start of FINTEPLA treatment
- Every 6 months with the completion of each echocardiogram
- 3 to 6 months after treatment discontinuation with the completion of the final echocardiogram

If valvular heart disease and/or pulmonary arterial hypertension is observed on an echocardiogram, the benefits versus the risks of initiating or continuing treatment with FINTEPLA should be considered.

Cardiovascular Adverse Events Reporting Form

During treatment, if findings consistent with vascular heart disease, pulmonary arterial hypertension, or any new abnormality have been reported on the Patient Status Form, FINTEPLA REMS will send a follow-up Cardiovascular Adverse Event Reporting Form to obtain all required data related to the adverse event that must be completed and returned to the FINTEPLA REMS within 3 business days of receipt.

- Valvular heart disease is indicated by mild or greater aortic regurgitation or moderate or greater mitral regurgitation
- Pulmonary arterial hypertension is indicated by elevated right heart/pulmonary artery pressure (pulmonary arterial systolic pressure >35 mm Hg)

This concludes the Prescriber Training.

FINTEPLA REMS

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(fenfluramine) CIV
2.2 mg/mL oral solution

FINTEPLA REMS Program Overview

This overview describes the requirements of the FINTEPLA REMS and the responsibilities of prescribers, pharmacies, and patients.

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

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

What Is the FINTEPLA REMS (Risk Evaluation and Mitigation Strategy)?

A REMS is a strategy to manage known or potential risks associated with a drug and is required by the US Food and Drug Administration (FDA) to ensure that the benefits of the drug outweigh its risks. FINTEPLA is available only through a restricted distribution program called the FINTEPLA REMS because of the risk of valvular heart disease and pulmonary arterial hypertension.

How Does the FINTEPLA REMS Work?

	To begin prescribing/ dispensing	Before starting FINTEPLA	During FINTEPLA treatment	After FINTEPLA discontinuation
Prescriber	• Prescriber certification	• **Counsel** the patient • **Enroll** the patient • **Assess** the patient's CV status via ECHO • **Document and submit** the ECHO results and authorization for treatment to the REMS	• **Counsel** the patient • **Assess** the patient's CV status via ECHO • **Document and submit** the ECHO results and authorization for treatment to the REMS • **Document and submit** ECHO results suggestive of VHD, PAH, or other new CV abnormalities to the REMS	• **Assess** the patient's CV status via ECHO • **Document and submit** the ECHO results to the REMS
Pharmacy (outpatient or inpatient)	• Pharmacy certification		• Before dispensing, **obtain authorization to dispense** by contacting the REMS	
Patient		• **Review** the *Patient Guide* • **Enroll** in the REMS with your healthcare provider • **Get an ECHO**	• **Get an ECHO every 6 months during treatment**	• **Get an ECHO**

CV, cardiovascular; ECHO, echocardiogram; PAH, pulmonary arterial hypertension; VHD, valvular heart disease.

What Are the Requirements of the FINTEPLA REMS?

Prescriber requirements	Pharmacy requirements	Patient requirements
• **Become certified** • As you start a patient on FINTEPLA, **counsel and enroll** the patient, evaluate baseline ECHO, and submit ECHO results to the REMS • Perform ongoing **monitoring of the patient's CV status via ECHO** every 6 months and once 3 to 6 months after treatment discontinuation • **Document and submit** the ECHO results and authorization for treatment to the REMS • **Document and submit** ECHO results suggestive of PAH, VHD, or other CV abnormalities to the REMS • **Report** treatment discontinuation or transfer of care to the REMS	• **Designate** an authorized representative to certify in the REMS • **Train** staff • Before dispensing, **obtain authorization to dispense** by contacting the REMS • Inpatient pharmacies, **dispense** no more than 15 days' supply at discharge • **Recertify** in the REMS if the authorized representative changes • **Comply** with audits	• **Understand** the risks associated with FINTEPLA • **Enroll** in the REMS with your healthcare provider • **Get an ECHO to check your heart** ° Before you start FINTEPLA ° Every 6 months to continue treatment ° Once 3 to 6 months after stopping treatment • **Tell** your healthcare provider if any signs or symptoms of PAH or VHD develop

CV, cardiovascular; ECHO, echocardiogram; PAH, pulmonary arterial hypertension; VHD, valvular heart disease.

What Are the FINTEPLA REMS Resources?

	To begin prescribing/ dispensing	Before starting FINTEPLA	During FINTEPLA treatment
Prescriber	• Prescribing Information • *REMS Program Overview* • *Prescriber Training* • *Prescriber Knowledge Assessment* • *Prescriber Enrollment Form*	• *Patient Status Form*	• *Patient Status Form* • *Cardiovascular Adverse Event Reporting Form*
Pharmacy (outpatient or inpatient)	• *Pharmacy Guide* • *REMS Program Overview* • *Outpatient Pharmacy Enrollment Form* • *Inpatient Pharmacy Enrollment Form*		
Patient		• *Patient Enrollment Form* • *Patient Guide*	

Phone: 1-877-964-3649 • www.FinteplaREMS.com • **Fax:** 1-833-568-6198

Reference ID: 4631810

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Phone: 1-877-964-3649 • www.FinteplaREMS.com • **Fax:** 1-833-568-6198

PRESCRIBER INFORMATION	* indicates required field.
First Name*:	Phone*:

PRESCRIBER ASSESSMENT
Answer the following questions by selecting the single best answer. You must answer ALL questions correctly to become certified in the REMS.

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FINTEPLA REMS

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

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 **R**isk **E**valuation and **M**itigation **S**trategy (**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.

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

Phone: 1-877-964-3649 • www.FinteplaREMS.com • **Fax:** 1-833-568-6198

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

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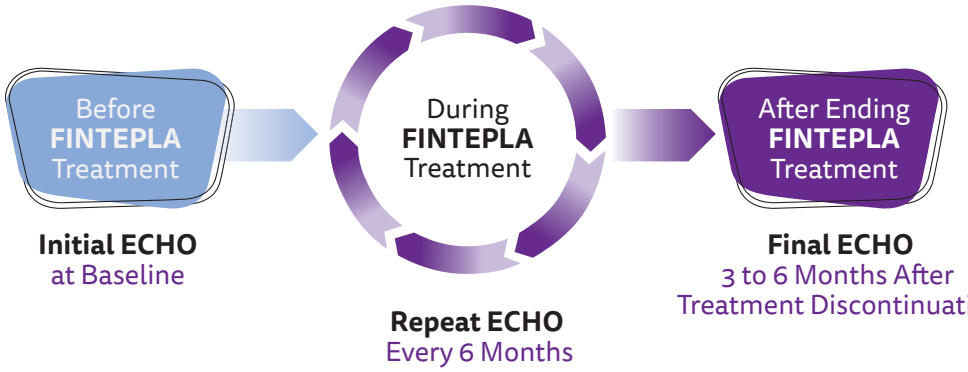
Reference ID: 4631810

FINTEPLA ECHO Monitoring Timeline



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).

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FINTEPLA REMS

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Pharmacy Guide

This guide describes the requirements of the FINTEPLA REMS and the responsibilities of pharmacies. For more information regarding the FINTEPLA REMS, please visit www.FinteplaREMS.com or call 1-877-964-3649.

Fintepla®
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2.2 mg/mL oral solution

What Is FINTEPLA?

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

Risk of valvular heart disease and pulmonary arterial hypertension

Valvular heart disease and pulmonary arterial hypertension have been associated with fenfluramine. 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. In clinical trials of FINTEPLA for the treatment of Dravet syndrome, no cases of valvular heart disease or pulmonary hypertension were reported. Across clinical trials of FINTEPLA for the treatment of Dravet syndrome, 0.4-1.6% of patients taking FINTEPLA were found to have trace aortic or mitral regurgitation compared with 0-6% of patients taking placebo. Trace aortic or mitral regurgitation is considered a physiologic or normal finding in the absence of valvular abnormalities.

Monitoring

- Prior to starting treatment, patients must undergo an echocardiogram to evaluate for valvular heart disease and pulmonary arterial hypertension
- Echocardiograms must be repeated every 6 months while a patient is taking FINTEPLA
- If FINTEPLA is discontinued, a follow-up echocardiogram must be performed once 3 to 6 months after the final dose
- If valvular heart disease and/or pulmonary arterial hypertension is observed on an echocardiogram, then the prescriber must consider the benefits versus the risks of initiating or continuing treatment with FINTEPLA

What Is the FINTEPLA REMS (Risk Evaluation and Mitigation Strategy)?

A REMS is a strategy to manage known or potential risks associated with a drug and is required by the US Food and Drug Administration (FDA) to ensure that the benefits of the drug outweigh its risks. FINTEPLA is available only through a restricted distribution program called the FINTEPLA REMS because of the risk of valvular heart disease and pulmonary arterial hypertension.

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What Are the FINTEPLA REMS Requirements?

- Healthcare providers must be certified in the REMS to prescribe FINTEPLA
- All patients must be enrolled in the REMS to receive FINTEPLA
- All pharmacies must be certified in the REMS to dispense FINTEPLA
- Before dispensing, pharmacies must obtain authorization to dispense by contacting the REMS to verify that the prescriber is certified, the patient is enrolled, and the patient is authorized to receive treatment
- Upon notice from the REMS, ALL pharmacies must provide complete and accurate requested REMS data such as patient, prescriber, prescription, and dispensing data on a timely basis but not longer than 15 calendar days. Inpatient pharmacies should provide the REMS with the patient's current dosing, quantity of FINTEPLA being dispensed at discharge, and discharge date by fax at 1-833-568-6198

How Does a Pharmacy Become Certified in the FINTEPLA REMS?

In order to become certified, the pharmacy must	1. Designate an authorized representative to carry out the certification process and oversee implementation and compliance with the REMS requirements on behalf of the pharmacy 2. Have the authorized representative review this *Pharmacy Guide* and the *REMS Program Overview* 3. Have the authorized representative enroll in the REMS by completing the *Outpatient Pharmacy Enrollment Form* or *Inpatient Pharmacy Enrollment Form*, as appropriate, and submitting it to the REMS 4. Train all relevant staff involved in dispensing FINTEPLA on the REMS requirements using this *Pharmacy Guide*

What Are the Responsibilities of Outpatient Pharmacies?

Before dispensing	1. Obtain authorization to dispense FINTEPLA by contacting the REMS to verify that the prescriber is certified, the patient is enrolled, and the patient is authorized to receive the drug
To maintain certification to dispense	2. Have the new authorized representative enroll in the REMS by completing the *Outpatient Pharmacy Enrollment Form* if the authorized representative changes
At all times	3. Not distribute, transfer, loan, or sell FINTEPLA, except to certified pharmacies 4. Maintain records that all processes and procedures are in place and being followed 5. Maintain records documenting staff's completion of REMS training 6. Maintain records of dispensing information including patient, prescriber, prescription, and dispensing data 7. Comply with audits carried out by Zogenix, Inc. or a third party acting on behalf of Zogenix, Inc. to ensure that all processes and procedures are in place and are being followed

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Reference ID: 4631810

What Are the Responsibilities of Inpatient Pharmacies?

Before dispensing	1. For patients initiating treatment: Obtain authorization to dispense FINTEPLA by contacting the REMS to verify that the prescriber is certified, the patient is enrolled, and the patient is authorized to receive the drug 2. To continue maintenance therapy: Obtain authorization to dispense FINTEPLA by contacting the REMS to verify that the patient is under the care of a certified prescriber, the patient is enrolled, and the patient is authorized to receive the drug
At discharge	3. Dispense no more than 15 days' supply
To maintain certification to dispense	4. Have the new authorized representative enroll in the REMS by completing the *Inpatient Pharmacy Enrollment Form* if the authorized representative changes
At all times	5. Not distribute, transfer, loan, or sell FINTEPLA 6. Maintain records that all processes and procedures are in place and being followed 7. Maintain records that document staff's completion of REMS training 8. Maintain records of dispensing information for all patients, including the patient's current dosing, quantity of FINTEPLA being dispensed at discharge, and discharge date. Provide this information to the REMS via fax when the patient is discharged 9. Comply with audits carried out by Zogenix, Inc. or a third party acting on behalf of Zogenix, Inc. to ensure that all processes and procedures are in place and are being followed 10. To order FINTEPLA, contact the REMS at 1-877-964-3649

Authorization to Dispense

To obtain authorization to dispense FINTEPLA, pharmacies can contact the REMS online using www.FinteplaREMS.com or by calling 1-877-964-3649. The REMS Coordinating Center will provide the patient's authorization status based on the prescriber's certification status, the patient's enrollment status, and the *Patient Status Form*. The prescriber completes and submits the *Patient Status Form* to the REMS before treatment initiation and every 6 months during treatment. The *Patient Status Form* provides documentation of the required echocardiogram monitoring and the prescriber's determination of appropriateness for treatment.

Authorized: The prescriber is certified, or the patient is under the care of a certified prescriber, the patient is enrolled, and the patient has a *Patient Status Form* on file with the REMS. The pharmacy may proceed with dispensing FINTEPLA.

Authorized—Warning: The prescriber is certified, or the patient is under the care of a certified prescriber, the patient is enrolled, and the patient has a *Patient Status Form* on file with the REMS that is overdue, but it is within the 90-day grace period. The pharmacy may proceed with dispensing FINTEPLA. The REMS Coordinating Center will contact the prescriber and patient to remind them of the required echocardiogram monitoring and that the *Patient Status Form* is overdue.

Not Authorized: The prescriber is not certified, the patient is not under the care of a certified prescriber, the patient is not enrolled, the patient does not have a *Patient Status Form* on file, the prescriber determined the patient is not authorized to receive FINTEPLA on the *Patient Status Form*, or the patient has a *Patient Status Form* more than 90 days overdue. Pharmacies must not dispense FINTEPLA to any patient with a status of "Not Authorized." Contact the REMS Coordinating Center at 1-877-964-3649 for assistance.

Additional Risks and Safety Information

The information presented in this guide does not include a complete list of all safety information for FINTEPLA. To review complete safety information on FINTEPLA, please refer to the Prescribing Information for FINTEPLA at www.FinteplaREMS.com.

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

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PATIENT INFORMATION	* indicates required field.
First Name*:	Address Line 1*:

PRESCRIBER INFORMATION	* indicates required field.
First Name*:	Address Line 1*:

FINTEPLA DOSING INFORMATION	* indicates required field.	
Current dose of FINTEPLA:	mg/kg/day	Total mg/day

ECHOCARDIOGRAM RESULTS	* indicates required field.			
Date of echocardiogram (MM/DD/YYYY)*: / /				
Regurgitation (check only 1 box per row) If echocardiogram report states “mild to moderate” or “moderate to severe,” check the more severe category.				
Valve	Absent/Trace	Mild	Moderate	Severe
☐ ☐	☐ ☐	☐ ☐	☐ ☐	☐ ☐
☐ ☐				

Authorization for Treatment

If this patient is not authorized to receive FINTEPLA, please provide the reason(s) (select all that apply)*

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PATIENT INFORMATION	* indicates required field.
First Name*:	Address Line 1*:

PRESCRIBER INFORMATION	* indicates required field.
First Name*:	Address Line 1*:

CARDIOVASCULAR ADVERSE EVENT INFORMATION	* indicates required field.
Cardiac findings on echocardiogram (select all that apply)*:	
☐ Valvular heart disease (VHD)	

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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Medication Guide Prescribing Information

LOGIN

PRESCRIBERS PHARMACIES PATIENTS CONTACT US RESOURCES

What is the FINTEPLA REMS (Risk Evaluation and Mitigation Strategy)?

The FINTEPLA REMS is a safety program to manage **risk of valvular heart disease and pulmonary arterial hypertension**. The REMS is required by the U.S. Food and Drug Administration (FDA) to ensure the potential benefits of FINTEPLA outweigh its risks.

FINTEPLA REMS Overview

- Only certified healthcare providers can prescribe FINTEPLA.
- Only certified pharmacies can dispense FINTEPLA.
- Educate patients on the risks of developing problems with the heart valves or high blood pressure in the arteries of the lungs.
- Enroll all patients in the REMS.

PRESCRIBERS

How to **prescribe** FINTEPLA

LEARN MORE

PHARMACIES

How to **dispense** FINTEPLA

LEARN MORE

PATIENTS

How to **receive** FINTEPLA

LEARN MORE

Insert indication statement from approved label.

To learn more about the serious risks associated with FINTEPLA, please refer to the Prescribing Information, Prescriber Training, Pharmacy Guide, and REMS Program Overview.

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

For FINTEPLA REMS Information contact:
Phone: 877 964 3649
Fax: 833 568-6198

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PRESCRIBERS

Prescriber Requirements

How do I become certified to prescribe FINTEPLA?

1. Review the following educational materials on FINTEPLA to understand the risk of valvular heart disease and pulmonary arterial hypertension associated with FINTEPLA:
   - Review the Prescribing Information
   - Review the Prescriber Training and REMS Program Overview
2. Successfully complete the Prescriber Knowledge Assessment and submit it to the REMS:
   - Online
   - Fax
   - By Mail
3. Enroll in the REMS by completing the Prescriber Enrollment form and submitting it to the REMS:
   - Online
   - Fax
   - By Mail

If the user selects Online, the system directs them to the Login screen. If the user selects Fax or Mail, the corresponding writeable PDF approved REMS Form loads (reference page 3 of this pdf to see completable form as an example). The user can complete the form, print, sign, and submit or the user can download the form to be completed at a later date.

PRESCRIBERS

PRESCRIBER PORTAL

LOGIN

How do I enroll a patient in the FINTEPLA REMS?

1. Counsel the patient on the risks of valvular heart disease and pulmonary arterial hypertension, including how to recognize and respond to signs and symptoms of valvular heart disease and pulmonary arterial hypertension, and the need for cardiac monitoring via echocardiogram at baseline (treatment initiation), every 6 months during treatment, and once 3 to 6 months after treatment discontinuation using the Patient Guide.
2. Provide the patient with the Patient Guide.
3. Enroll the patient by completing and submitting the Patient Enrollment Form to the REMS:
   - Online
   - Fax
   - By Mail
4. Assess the patient's cardiovascular status and the appropriateness of initiating treatment by obtaining an echocardiogram. Document and submit the results and authorization for treatment to the REMS, using the Patient Status Form:
   - Online
   - Fax
   - By Mail

To ensure compliance with FINTEPLA REMS requirements, healthcare providers must:

During treatment: Every 6 months

1. Counsel the patient on the need for cardiac monitoring via echocardiogram every 6 months during treatment using the Patient Guide.
2. Assess the patient's cardiovascular status and the appropriateness of continuing treatment by obtaining an echocardiogram. Document and submit the results and appropriateness of continued treatment to the REMS using the Patient Status Form.

After treatment discontinuation: 3 to 6 months

1. Assess the patient's cardiovascular status by obtaining an echocardiogram. Document and submit the results to the REMS using the Patient Status Form.

At all times

1. Report adverse events suggestive of valvular heart disease and/or pulmonary arterial hypertension on the Cardiovascular Adverse Event Reporting Form to the REMS.
2. Report treatment discontinuation or transfer of care to the REMS.

Reference ID: 4631810

FINTEPLA REMS Prescriber Enrollment Form

FOR PRESCRIBERS

Instructions

1. Review the FINTEPLA Prescribing Information, *Prescriber Training,* and *REMS Program Overview*
2. Successfully complete and submit the *Prescriber Knowledge Assessment* and this *Prescriber Enrollment Form* online at www.FinteplaREMS.com or fax to 1-833-568-6198 or mail to 1710 N Shelby Oaks Dr, Ste 3, Memphis, TN 38134
3. Complete all required fields on this form to avoid a delay in the enrollment process. Upon completion of these steps, the REMS will notify you of your successful certification within 2 business days

PRESCRIBER INFORMATION

* indicates required field.

First Name*:	Practice/Facility Name*:
Last Name*:	Address Line 1*:
Degree*: ☐ MD ☐ DO ☐ NP ☐ PA ☐ Other (please specify) _____	Address Line 2:
Prescriber's DEA Number*:	City*: State*: ZIP Code*:
National Provider Identifier (NPI)*:	Practice/Facility Phone*: - -
State License Number:	Practice/Facility Fax*: - -
Prescriber Email*:	Primary Contact at Office First Name:
Specialty*: ☐ Adult Neurology ☐ Pediatric Neurology ☐ Adult Epileptology ☐ Pediatric Epileptology ☐ Other (please specify) _____	Primary Contact at Office Last Name: Primary Contact Title: Are primary contact phone and fax numbers different from practice/facility phone and fax numbers? (If yes, please complete the following 2 fields) No ☐ Yes ☐
Preferred Method of Communication: ☐ Email ☐ Phone ☐ Fax	Primary Contact Direct Phone Number: - -
Primary Contact Email:	Primary Contact Fax Number: - -

PRESCRIBER AGREEMENT

By completing, signing, and submitting this form, I agree to comply with the following REMS requirements:

- Review the FINTEPLA *Prescribing Information (PI), Prescriber Training,* and *REMS Program Overview*
- Successfully complete the *Prescriber Knowledge Assessment* and submit it to the REMS
- Enroll in the REMS by completing this form

Before treatment initiation, to prescribe FINTEPLA to a patient, I will:

- Give the patient a copy of the *Patient Guide*
- Counsel the patient on the risks of valvular heart disease and pulmonary arterial hypertension, including how to recognize and respond to signs and symptoms of valvular heart disease and pulmonary arterial hypertension, and the need for cardiac monitoring via echocardiogram at baseline (treatment initiation), every 6 months during treatment, and once 3 to 6 months after treatment discontinuation using the *Patient Guide*
- Enroll the patient by completing and submitting the *Patient Enrollment Form* to the REMS
- Assess the patient's cardiovascular status and the appropriateness of initiating treatment by obtaining an echocardiogram. Document and submit the results and authorization for treatment to the REMS using the *Patient Status Form*

During treatment, every 6 months, I will:

- Counsel the patient on the need for cardiac monitoring via echocardiogram every 6 months during treatment and once 3 to 6 months after treatment discontinuation using the *Patient Guide*
- Assess the patient's cardiovascular status and the appropriateness of continuing treatment by obtaining an echocardiogram. Document and submit the results and appropriateness of continued treatment to the REMS using the *Patient Status Form*

After treatment discontinuation, within 3 to 6 months, I will:

- Assess the patient's cardiovascular status by obtaining an echocardiogram. Document and submit the results to the REMS using the *Patient Status Form*

At all times, I will:

- Report cardiovascular adverse events suggestive of valvular heart disease and pulmonary arterial hypertension to the REMS
- Report treatment discontinuation or transfer of care to the REMS

_____ / /

Signature **Date**

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Medication Guide Prescribing Information

LOGIN

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Login

User Name

Password

Forgot password?

Login

New Prescriber User? Click here to Create Login

New Pharmacy User? Click here to Create Login

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Medication Guide Prescribing Information

LOGIN

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PRESCRIBERS

Create Login

FINTEPLA is available only through the FINTEPLA Risk Evaluation and Mitigation Strategy (REMS) program. If you have any questions, please contact the FINTEPLA REMS Program at 877-964-3649 Monday through Friday between 7AM - 7PM Central Time.

To submit this form, please complete all required fields below. Required fields are denoted by"*".

Prescriber Information

National Provider Identifier (NPI) Number *

LOOKUP RESET

First Name *

Last Name *

Prescriber Email *

Re-enter Prescriber Email *

I'm not a robot reCAPTCHA Privacy - Terms

Create Login

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Medication Guide Prescribing Information

Hello, UserName@email.com Change Password | Logout

PRESCRIBERS PHARMACIES PATIENTS CONTACT US RESOURCES

This allows the prescriber to access online forms after login to the website.

Tools

REMS Prescriber Knowledge Assessment Certification

START

Documents

Prescriber Training
REMS Program Overview
Prescriber Knowledge Assessment
Prescriber Enrollment Form
Patient Enrollment Form
Patient Guide

Patient Status Form
Cardiovascular Adverse Event Reporting Form
Letter for Healthcare Providers
Prescribing Information

ZOGENIX

Reference ID: 4631810

PRESCRIBERS

Prescriber Knowledge Assessment

FINTEPLA is available only through the FINTEPLA Risk Evaluation and Mitigation Strategy (REMS).

If you have any questions or need additional information, please call 1-877-964-3649, Monday through Friday 7 AM - 7 PM Central Time.

Instructions

1. Review the FINTEPLA's Prescribing Information, the Prescriber Training and REMS Program Overview.
2. Successfully complete and submit this Prescriber's Knowledge Assessment at www.FinteplaREMS.com or fax to 1-833-568-6198 or mail to 1710 N Shelby Oaks Dr, Suite 3, Memphis, TN 38134.
3. Complete all required fields on this form to avoid delay in the enrollment process.

Prescriber Knowledge Assessment

Answer the following questions by selecting the 1 best answer. You must answer ALL questions correctly to become certified in the REMS.

You will have 3 tries to successfully complete the Prescriber Knowledge Assessment.

If you do not successfully complete the Prescriber Knowledge Assessment you will need to review the Prescriber Training and REMS Program Overview.

To submit this form, please complete all required fields below. Required fields are denoted by"*".

Prescriber Information

National Provider Identifier (NPI) Number *

First Name *

Last Name *

Phone *

Email *

SAVE and START Test

ZOGENIX

Prescriber Knowledge Assessment

Answer the following questions by selecting the 1 best answer. You must answer all 9 questions correctly to become certified in the FINTEPLA REMS.

Question 1:

The goal of the REMS is to mitigate the risk of valvular heart disease and pulmonary arterial hypertension.

- ○ True
- ○ False

Question 2:

In order to receive FINTEPLA, patients must enroll in REMS.

- ○ True
- ○ False

Question 3:

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

- ○ True
- ○ False

Question 4:

The signs and symptoms for valvular heart disease and pulmonary arterial hypertension may include:

- ○ Shortness of breath
- ○ Fatigue
- ○ Dizziness or fainting
- ○ Swelling of ankles and feet
- ○ Rapid heartbeat
- ○ All of the above

Question 5:

A patient must obtain an echocardiogram at baseline (treatment initiation), every 6 months during treatment, and once 3 to 6 months after treatment discontinuation.

- ○ True
- ○ False

Question 6:

I don't need to document the results of the echocardiogram for each patient on the Patient Status Form in order to prescribe FINTEPLA.

- ○ True
- ○ False

Question 7:

I may be contacted by the REMS program for further information regarding any reports of valvular heart disease and pulmonary arterial hypertension.

- ○ True
- ○ False

Question 8:

Only pharmacies certified in the REMS may dispense FINTEPLA to patients.

- ○ True
- ○ False

Question 9:

An echocardiogram can identify evidence of valvular heart disease or pulmonary arterial hypertension prior to a patient becoming symptomatic.

- ○ True
- ○ False

Click to Submit and continue to Certification

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PRESCRIBERS

FINTEPLA REMS Prescriber Knowledge Assessment Results

Prescribers who successfully complete the Prescriber Knowledge Assessment will receive:

You have successfully completed the Prescriber Knowledge Assessment.
You must complete the Prescriber Enrollment and submit to the REMS before prescribing FINTEPLA.
Enrollment and certification in the REMS will be confirmed within 2 business days.

Continue to Certification

Prescribers who did not achieve 100% will be presented the message below:

You did not achieve 100%; you must retake the Prescriber Knowledge Assessment.
You must successfully complete the Prescriber Knowledge Assessment within 3 attempts or you must review the Prescriber Training and REMS Program Overview in order to retake the Prescriber Knowledge Assessment.

Review The Documents Retake The Test

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PRESCRIBERS

Prescriber Enrollment Form

Instructions

1. Review the FINTEPLA Prescribing Information, Prescriber Training, and REMS Program Overview.
2. Successfully complete and submit the Prescriber Knowledge Assessment and this Prescriber Enrollment Form online at www.FinteplaREMS.com or fax to 1-833-568-6198 or mail to 1710 N Shelby Oaks Dr, Suite 3, Memphis, TN 38134.
3. Complete all required fields on this form to avoid a delay in the enrollment process. Upon completion of these steps, the REMS will notify you upon successful certification within 2 business days.

To submit this form, please complete all required fields below. Required fields are denoted by"*".

Prescriber Information

National Provider Identifier (NPI) Number *

LOOKUP RESET

First Name * Last Name * Prescriber Email *

Prescribers' Drug Enforcement Administration (DEA) Number * State License Number

Practice/Facility Name *

Address Line 1 *

Address Line 2

City * State * - Select - ZIP Code *

Practice/Facility Phone * Practice/Facility Fax *

Degree: *
- Doctor of Medicine (MD)
- Doctor of Osteopathic Medicine (DO)
- Nurse Practitioner (NP)
- Physician Assistant (PA)
- Other

Specialty: *
- Adult Neurology
- Adult Epileptology
- Pediatric Neurology
- Pediatric Epileptology
- Other

Primary Contact at Office

First Name Last Name Title

Preferred method of communication E-mail Phone Fax

Primary Contact Email

Are primary contact phone and fax numbers different from practice/facility phone and fax numbers? No Yes

(If yes, please complete the following 2 fields)

Direct Telephone Number Fax Number

Prescriber Agreement

By completing, signing, and submitting this form, I agree to comply with the following REMS requirements:

- Review the FINTEPLA Prescribing Information (PI), Prescriber Training, and REMS Program Overview.
- Successfully complete the Prescriber Knowledge Assessment and submit to the REMS.
- Enroll in the REMS by completing this form.

Before treatment initiation, to prescribe FINTEPLA to a patient, I will:

- Give the patient a copy of the Patient Guide.
- Counsel the patient on the risks of valvular heart disease and pulmonary arterial hypertension, including how to recognize and respond to signs and symptoms of valvular heart disease and pulmonary arterial hypertension, and the need for cardiac monitoring via echocardiogram at baseline (treatment initiation), every 6 months during treatment, and once 3 to 6 months after treatment discontinuation using the Patient Guide.
- Enroll the patient by completing and submitting the Patient Enrollment Form to the REMS.
- Assess the patient's cardiovascular status and the appropriateness of initiating treatment by obtaining an echocardiogram. Document and submit the results and authorization for treatment to the REMS using the Patient Status Form.

During treatment, every 6 months, I will:

1. Counsel the patient on the need for cardiac monitoring via echocardiogram every 6 months during treatment and once 3 to 6 months after treatment discontinuation using the Patient Guide.
2. Assess the patient's cardiovascular status and the appropriateness of continuing treatment by obtaining an echocardiogram. Document and submit the results and appropriateness of continued treatment to the REMS using the Patient Status Form.

After treatment discontinuation, within 3 to 6 months, I will:

- Assess the patient's cardiovascular status by obtaining an echocardiogram. Document and submit the results to the REMS using the Patient Status Form.

At all times, I will:

1. Report cardiovascular adverse events suggestive of valvular heart disease and pulmonary arterial hypertension to the REMS.
2. Report treatment discontinuation or transfer of care to the REMS.

Select Signing Reason - Select - I approve this document

Signature *

21CFR Part II requires a reason for signing the document

SUBMIT

ZOGENIX

PRESCRIBERS

Patient Enrollment Form

Instructions
Complete this form with your healthcare provider and submit:
- Online at www.FinteplaREMS.com
- By fax to 1-833-568-6198
- By mail to 1710 N Shelby Oaks Dr., Ste 3, Memphis, TN 38134

To submit this form, please complete all required fields below. Required fields are denoted by"*".

Patient Information

First Name *
Last Name *
Date of Birth (MM/DD/YYYY) *
Gender: *
○ Male ○ Female ○ Neutral ○ Prefer not to say

RACE *
○ Black or African American ○ White ○ American Indian or Alaska Native
○ Asian ○ Native Hawaiian or Other Pacific Islander ○ Other (please specify)

ETHNICITY * ○ Hispanic or Latino ○ Not Hispanic or Latino

Street Address, line 1 *
Street Address, line 2
City *
State * - Select -
Zip *

PHONE *
Home Telephone
Work Telephone
Cell Phone

E-mail *

Best Time to Call: ○ AM ○ PM

Okay to Leave Message: * ○ Yes ○ No

Legal Guardian Name:
Relationship:
Legal Guardian Phone:
Legal Guardian Email:

Prescriber Information

National Provider Identifier (NPI) Number * LOOKUP RESET

First Name *
Last Name *
REMS ID:*
Prescriber Email
Prescriber Phone *
Prescriber Fax *
Address Line 1 *
Address Line 2
City *
State * - Select -
ZIP Code *

Patient Agreement

I have received, read, and understand the Patient Guide that my healthcare provider has given me.

Before my treatment begin:
- I will Enroll in the REMS by completing this Patient Enrollment Form with my healthcare provider.
- I will get an echocardiogram (ECHO) to check my heart.

My healthcare provider has counseled me on:
- The risk of developing heart valve problems and high blood pressure in my lung arteries.
- Recognizing the signs and symptoms associated with these risks.
- Importance of me getting a test called an echocardiogram (ECHO) before starting FINTEPLA, every 6 months during treatment, and once 3 to 6 months after I stop treatment.

During treatment, every 6 months:
- I will receive counseling from my healthcare provider on the importance of getting an echocardiogram (ECHO).
- I will get an echocardiogram (ECHO) to check my heart.

After stopping treatment, 3 to 6 months after my final dose:
- I will get one last echocardiogram (ECHO) to check my heart.

At all times:
- I will let all my healthcare providers know that I am taking FINTEPLA.

I will also tell my healthcare provider if I am having any of these signs or symptoms:
- Shortness of breath
- Rapid heartbeat
- Fatigue
- Swelling of ankles and feet
- Dizziness or fainting spells
- Chest pressure or pain

I understand that:
- Zogenix, Inc. and its agents may contact me via phone, mail, fax, or email to support administration of the REMS.
- Zogenix, Inc. and its agents may use and share my personal health information, including echocardiogram (ECHO) results and prescription data collected as part of the REMS for the purpose of operations, analysis, and reporting of the REMS including enrolling me into, administering, and evaluating the REMS, coordinating the dispensing of FINTEPLA, and releasing my personal health information to the Food and Drug Administration (FDA), as necessary.
- In order to receive FINTEPLA, I am required to be enrolled in the REMS, and my information will be stored in a database of all participants who receive FINTEPLA in the United States.

Select Signing Reason - Select -

☐ Parent or Legal Guardian Signature *
☐ Patient Signature (if applicable)

SUBMIT

Prescriber Agreement
By signing below, I acknowledge that I have reviewed the risks of FINTEPLA and the requirements of the FINTEPLA REMS with this patient.

Select Signing Reason - Select -

☐ Prescriber Signature *

SUBMIT

PRESCRIBERS

Patient Status Form

Prior to starting and during treatment, patients must undergo an echocardiogram (ECHO) to evaluate for cardiac abnormalities. The prescriber must consider the benefits versus the risks of initiating or continuing treatment with FINTEPLA if ANY of the following signs are observed on an echocardiogram:

- Valvular heart disease (VHD) as indicated by mild or greater aortic regurgitation or moderate or greater mitral regurgitation
- Pulmonary arterial hypertension (PAH) as indicated by elevated right heart/pulmonary artery pressure [PASP > 35mm Hg]

Instructions

This form must be regularly completed for all patients treated with FINTEPLA:

- Before the start of FINTEPLA treatment.
- With completion of each echocardiogram every 6 months for the duration of FINTEPLA treatment.
- With completion of echocardiogram performed 3 to 6 months after the final dose of FINTEPLA.

Submit the completed form online at www.FinteplaREMS.com, via fax to 1-833-568-6198, or via mail to 1710 N Shelby Oaks Dr, Ste 3, Memphis, TN 38134.

If you have any questions or need additional information, please visit www.FinteplaREMS.com or call 1-877-964-3649, Monday through Friday between 7 AM–7 PM Central Time.

To submit this form, please complete all required fields below. Required fields are denoted by"*".

Patient Information

First Name * | Last Name * | REMS ID

Date of Birth (MM/DD/YYYY) *

Street Address, line 1 *

Street Address, line 2

City * | State * - Select - | Zip *

Height: | Weight: | BMI

Prescriber Information

First Name * | Last Name * | REMS ID

National Provider Identifier (NPI) *

Street Address, line 1 *

Street Address, line 2

City * | State * - Select - | Zip *

Telephone Number * | Fax Number * | E-mail

FINTEPLA Dosing Information

Current Dose of FINTEPLA:

mg/kg/day | Total mg/day | Current Duration of treatment with FINTEPLA:

Echocardiogram Results

Date of ECHO (MM/DD/YYYY) *

Regurgitation (check only 1 box per row)
If echocardiogram report states "mild to moderate" or "moderate to severe," check the more severe category. *

VALVE	Absent/Trace	Mild	Moderate	Severe
AORTIC	○	○	○	○
MITRAL	○	○	○	○

Elevated pulmonary arterial systolic pressure (PASP > 35 mm Hg): (select one) *	○ Yes	○ No
Any valvular abnormality reported on on baseline echocardiogram (only applicable to baseline echocardiogram assessment)	○ Yes	○ No
Any new abnormality on echocardiogram (not previously reported)	○ Yes	○ No

Authorization for Treatment

Is this patient authorized to receive FINTEPLA? (select one) * ○ Yes ○ No

If this patient is not authorized to receive FINTEPLA, please provide the reason(s): (select all that apply) *

- ☐ Changes in the echocardiogram or abnormal echocardiogram
- ☐ New diagnosis of VHD or PAH
- ☐ Noncompliance with echocardiogram
- ☐ Other (please specify)

If findings consistent with VHD, PAH or any new abnormality have been reported on the echocardiogram, Zogenix, Inc. will send a follow-up Cardiovascular Adverse Event Reporting Form that must be completed and returned to the FINTEPLA REMS within 3 business days of receipt.

Submitted by: * ○ Prescriber Designee ○ Prescriber

Select Signing Reason - Select -

☐ Signature *

SUBMIT

ZOGENIX

PRESCRIBERS

Cardiovascular Adverse Event Reporting Form

My patient's most recent echocardiogram observed signs of valvular heart disease (VHD), pulmonary arterial hypertension (PAH) or other cardiac findings in the echocardiogram.

Instructions

Within 3 business days of receipt, complete this form and submit the completed form online at www.FinteplaREMS.com, via fax to 1-833-568-6198, or via mail to 1710 N Shelby Oaks Dr, Ste 3, Memphis, TN 38134.

If you have any questions or need additional information, please visit www.FinteplaREMS.com or call 1-877-964-3649, Monday through Friday between 7 AM–7 PM Central Time.

To submit this form, please complete all required fields below. Required fields are denoted by"*".

Patient Information

First Name * | Last Name * | REMS ID *

Date of Birth (MM/DD/YYYY) *

Street Address, line 1 *

Street Address, line 2

City * | State * - Select - | Zip *

Prescriber Information

First Name * | Last Name * | REMS ID *

National Provider Identifier (NPI)*

Street Address, line 1*

Street Address, line 2

City * | State * - Select - | Zip *

Telephone Number * | Fax Number * | E-mail

Cardiovascular Adverse Event Information

*** Cardiac findings on echocardiogram (select all that apply):**

☐ **Valvular heart disease (VHD)**

☐ Mild or greater aortic regurgitation
(State degree of aortic regurgitation:)

☐ Moderate or greater mitral regurgitation
(State degree of mitral regurgitation:)

☐ Restricted valve motion (aortic and mitral valves)
(Which valve(s)?:)

☐ Valve thickening (aortic and mitral valves)
(Which valve(s)?:)

☐ **Pulmonary Arterial Hypertension (PAH)**
Echocardiogram findings of PAH (Select all that apply)

☐ Interventricular septal flattening

☐ Elevated right heart/pulmonary artery pressure (pulmonary artery systolic pressure >35 mm Hg)
(PASP reading was ____ mmHG)

☐ Other (please specify)

☐ **Other cardiac valve abnormalities (select all that apply):**

☐ Mild or greater pulmonic valve regurgitation (State degree of regurgitation:)

☐ Moderate or greater tricuspid valve regurgitation (State degree of regurgitation:)

☐ Other (please specify):

Dose of FINTEPLA at the time of the event: * mg/kg/day * and mg/day *

Is patient on concomitant Stiripentol? * ○ Yes ○ No

Duration of treatment with FINTEPLA (provide treatment dates): *

Was treatment discontinued due to this event? * ○ Yes ○ No

Was the patient symptomatic? * ○ Yes ○ No
If yes, please describe symptoms:

Were there any signs on physical exam? * ○ Yes ○ No
If yes, please describe signs:

☐ **Did the VHD, PAH, or other cardiac valve abnormalities result in any of the following (check all that apply):**

☐ Medication or interventional therapy ☐ Discontinuation of treatment

☐ Hospitalization ☐ No change

☐ Death

If an event of VHD or PAH or other cardiac abnormality is reported, the patient's prescriber will be contacted for further information regarding the report. Pertinent echocardiogram and laboratory test results will be required to be sent to the FINTEPLA REMS.

Submitted by: * ○ Prescriber Designee ○ Prescriber

Select Signing Reason - Select -

If the patient has been discontinued from FINTEPLA treatment, the prescriber/prescriber delegate must notify the FINTEPLA REMS.

☐ Signature *

SUBMIT

ZOGENIX

PHARMACIES

Create Login

FINTEPLA is available only through the FINTEPLA Risk Evaluation and Mitigation Strategy (REMS) program. If you have any questions, please contact the FINTEPLA REMS Program at 877-964-3649 Monday through Friday between 7AM - 7PM Central Time.

To submit this form, please complete all required fields below. Required fields are denoted by"*".

Pharmacy Information

Pharmacy Name *

Pharmacy National Provider Information (NPI): *

Authorized Representative Information

First Name *

Last Name *

Email *

Confirm Email *

I'm not a robot reCAPTCHA Privacy - Terms

Create Login

ZOGENIX

PHARMACIES

Outpatient Pharmacy Requirements

How do I become certified to dispense FINTEPLA?

1. Designate an authorized representative to carry out the certification process and oversee implementation and compliance with the REMS on behalf of the pharmacy.
2. Have the authorized representative review the Pharmacy Guide and REMS Program Overview.
3. Have the authorized representative enroll in the REMS by completing the Outpatient Pharmacy Enrollment Form and submitting it to the REMS.
   - Online
   - Fax
   - By Mail
4. Train all relevant staff involved in dispensing FINTEPLA on the REMS requirements using the Pharmacy Guide.

To Ensure Compliance with the FINTEPLA REMS Requirements, Pharmacies must:

Before dispensing FINTEPLA

1. Obtain authorization to dispense by contacting the REMS to verify that the prescriber is certified, and the patient is enrolled, and authorized to receive the drug.

To maintain certification to dispense

1. Have the new authorized representative enroll in the REMS by completing the Outpatient Pharmacy Enrollment Form if the authorized representative changes.

At all times

1. Not distribute, transfer, loan, or sell FINTEPLA, except to certified pharmacies.
2. Maintain records of dispensing information.
3. Maintain records that all processes and procedures are in place and being followed.
4. Maintain records documenting staff's completion of REMS training.
5. Comply with audits carried out by Zogenix, Inc. or a third party acting on behalf of Zogenix, Inc. to ensure that all processes and procedures are in place and are being followed.

Inpatient Pharmacy Requirements:

How do I become certified to dispense FINTEPLA?

1. Designate an authorized representative to carry out the certification process and oversee implementation and compliance with the REMS requirements on behalf of the pharmacy.
2. Have the authorized representative review the Pharmacy Guide and REMS Program Overview.
3. Have the authorized representative enroll in the REMS by completing the Inpatient Pharmacy Enrollment Form and submitting it to the REMS.
   - Online
   - Fax
   - By Mail
4. Train all relevant staff involved in dispensing FINTEPLA on the REMS requirements using the Pharmacy Guide.

To Ensure Compliance with the REMS Requirements Pharmacies must:

Before dispensing FINTEPLA

1. For patients initiating treatment: Obtain authorization to dispense each prescription by contacting the REMS to verify that the prescriber is certified, and the patient is enrolled and authorized to receive the drug.
2. For patient continuing treatment: Obtain authorization to dispense each prescription by contacting the REMS to verify that the patient is enrolled and authorized to receive the drug.

At discharge

1. Dispense no more than 15 days' supply.

To maintain certification to dispense

1. Have the new authorized representative enroll in the REMS by completing the Inpatient Pharmacy Enrollment Form if the authorized representative changes.

At all times

1. Not distribute, transfer, loan, or sell FINTEPLA.
2. Maintain records of dispensing information
3. Maintain records that all processes and procedures are in place and being followed.
4. Maintain records documenting staff's completion of REMS training.
5. Comply with audits carried out by Zogenix, Inc. or a third party acting on behalf of Zogenix, Inc. to ensure that all processes and procedures are in place and are being followed.

OUTPATIENT PHARMACY

Outpatient Pharmacy Enrollment Form

To become a FINTEPLA REMS certified pharmacy, enroll by following these steps:

STEP 1: REVIEW

- Designate an Authorized Representative.
- Authorized Representative review the Pharmacy Guide and REMS Program Overview.

STEP 2: COMPLETE AND SIGN

- The Authorized Representative must complete and sign this Outpatient Pharmacy Enrollment Form.
- If the Authorized Representative changes, the new Authorized Representative must complete and sign a new Outpatient Pharmacy Enrollment Form.

STEP 3: SUBMIT

- Submit the form via:
  - Online at www.FinteplaREMS.com or
  - Via fax to 1-833-568-6198 or
  - Via mail to 1710 N Shelby Oaks Dr, Suite 3, Memphis, TN 38134

To submit this form, please complete all required fields below. Required fields are denoted by"*".

Pharmacy Name * | National Provider Identifier (NPI) * | Pharmacy DEA Number *

Street Address, line 1 *

Street Address, line 2

City * | State * - Select - | Zip *

Telephone Number * | Fax Number * | E-mail

Authorized Representative Information

First Name * | Last Name *

Credentials * ○ R.PH ○ PharmD ○ BCPS ○ Other (please specify)

Telephone Number * | Fax Number | E-mail *

Preferred Method of Communication: ○ Phone ○ Fax ○ Email

Authorized Pharmacy Representative Agreement:

I am the Authorized Representative designated by my outpatient pharmacy to coordinate the activities of the REMS.

By completing, signing, and submitting this form on behalf of myself and my outpatient pharmacy, I attest that:

- I have reviewed the Pharmacy Guide and REMS Program Overview.
- I am enrolling in the REMS.
- I agree to train all relevant staff involved in dispensing FINTEPLA on the REMS requirements using the Pharmacy Guide.
- I will ensure that, before dispensing, all pharmacy staff obtain authorization to dispense each prescription by contacting the FINTEPLA REMS to verify the prescriber is certified and the patient is enrolled and authorized to receive FINTEPLA.
- I agree to ensure that all pharmacy staff do not distribute, transfer, loan, or sell FINTEPLA except to certiied pharmacies.
- I will maintain records of dispensing information.
- I will maintain records documenting staff's completion of REMS training.
- I will maintain records that all REMS processess and procedures are in place and being followed.
- I will ensure that all pharmacy staff comply with audits carried out by Zogenix, Inc. or a third party acting on behalf of Zogenix, Inc. to ensure that all processes and procedures are in place and are being followed.
- If the authorized representative changes, this pharmacy will have the new authorized representative enroll in the REMS by completing the Outpatient Pharmacy Enrollment Form.

Select Signing Reason - Select -

☐ Signature *

SUBMIT

ZOGENIX

INPATIENT PHARMACY

Inpatient Pharmacy Enrollment Form

To become a FINTEPLA REMS certified pharmacy, enroll by following these steps:

STEP 1: REVIEW

- Designate an Authorized Representative.
- The Authorized Representative review the Pharmacy Guide and REMS Program Overview.

STEP 2: COMPLETE AND SIGN

- The Authorized Representative must complete and sign this Inpatient Pharmacy Enrollment Form.
- If the Authorized Representative changes, the new Authorized Representative must complete and sign an new Inpatient Pharmacy Enrollment Form.

STEP 3: SUBMIT

- Submit this form either:
  - Online at www.FinteplaREMS.com or
  - Via fax to 1-833-568-6198 or
  - Via mail to 1710 N Shelby Oaks Dr, Suite 3, Memphis, TN 38134

To submit this form, please complete all required fields below. Required fields are denoted by"*".

Pharmacy Name *

Pharmacy National Provider Information (NPI): *

Pharmacy DEA Number *

Street Address, line 1 *

Street Address, line 2

City *

State * - Select -

Zip *

Telephone Number *

Fax Number *

E-mail

Authorized Representative Information

First Name *

Last Name *

Credentials * R.PH PharmD BCPS Other (please specify)

Telephone Number *

Fax Number

E-mail *

Preferred method of contact: Phone Fax Email

Authorized Pharmacy Representative Agreement:

I am the authorized representative designated by my inpatient pharmacy to coordinate the activities of the REMS.

By completing, signing, and submitting this form on behalf of myself and my inpatient pharmacy, I attest that:

- I have reviewed the Pharmacy Guide and REMS Program Overview.
- I am enrolling in the REMS
- I agree to train all relevant staff involved in dispensing FINTEPLA on the REMS requirements using the Pharmacy Guide.
- For patients initiating treatment: Before dispensing, all pharmacy staff must obtain authorization to dispense each prescription by contacting the FINTEPLA REMS to verify the prescriber is certified, and the patient is enrolled and authorized to receive FINTEPLA.
- For patients continuing treatment: Before dispensing, all pharmacy staff must obtain authorization to dispense each prescription by contacting the REMS to verify that the patient is under the care of a certified prescriber, and the patient is enrolled and authorized to receive FINTEPLA.
- I will not dispense more than 15 days' supply at discharge.
- I agree to ensure that all pharmacy staff do not distribute, transfer, loan or sell FINTEPLA.
- I will maintain records of dispensing information.
- I will maintain records documenting staff's completion of REMS training.
- I will maintain records that all REMS processes and procedures are in place and being followed.
- I will ensure that all pharmacy staff comply with audits carried out by Zogenix, Inc. or a third party acting on behalf of Zogenix, Inc. to ensure that all processes and procedures are in place and are being followed.
- If the authorized representative changes, this pharmacy will have the new authorized representative enroll in the REMS by completing the Inpatient Pharmacy Enrollment Form.

Select Signing Reason - Select -

☐ * Signature

SUBMIT

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

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Medication Guide Prescribing Information

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PRESCRIBERS PHARMACIES PATIENTS CONTACT US RESOURCES

PHARMACIES - HOME

Tools

Verify Prescriber Certification & Patient Enrollment

VERIFY

Obtain Dispense Authorization Number

START

ZOGENIX

Reference ID: 4631810

Prescriber

First Name | Last Name | National Provider Identifier (NPI)

Search Reset

Prescriber List

	HCP ID	First Name ▲	Last Name	State License No	State of License	NPI
Select	19	ADAM	NUMIS	A116439	CA	1093943508
Select	18	AIMEE	LUAT	4301082592	MI	1326216821
Select	50	ALAN	FREEMAN	26271	GA	1124132766
Select	29	ANDREW	SHEILS	13081	GA	1982677951
Select	15	ASIM	SHAHID	35.094552	OH	1962616730
Select	16	DAVID	BURKHOLDER	52949	MN	1598995722
Select	26	Dialecti	Voudouris			1174575187
Select	27	DINESH	TALWAR	20354	AZ	1831168566
Select	1	DOUGLAS	SMITH	60589	MN	1518285725

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Patient List

Patient First Name | Patient Last Name | REMS ID

MRN | DOB

Search Reset

Patients

	HubId	MRN	Patient First Name	Patient Last Name	Patient DOB
Select	19		Alice	Test-One	01/02/2018
Select	14		Amy	Test-Nineteen	02/02/2017
Select	18		Ann	Gatestone	02/15/2019
Select	22		Bob	TestTwo	02/04/2018
Select	17		Catherine	Test-Twentyfive	03/10/2013

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Medication Guide Prescribing Information

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PRESCRIBERS PHARMACIES PATIENTS CONTACT US RESOURCES

Patient List

Patient First Name

MRN

Search Reset

Patient Authorized to Receive FINTEPLA

Do you want a Dispense Authorization number for the selected Patient?

Yes No

If the Pharmacy checks YES they will go on to page 22

Patients

	HubId	MRN	Patient First Name	Patient Last Name	Patient DOB
Select	22		Bob	TestTwo	02/04/2018

1 - 1 of 1 items

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ZOGENIX

Dispense Authorization Number

Back

Patient and Provider Information

Patient First Name	Anee	Provider First Name	THOMAS
Patient Last Name	e	Provider Last Name	OUELLETTE
DOB	05/20/2019	NPI	1231231231
Patient Echo Due Date	06/18/2020	Certification Expiration Date	07/12/2021
Last Echo Completion Date			

Patient Dispense Authorization Information

Patient Status:

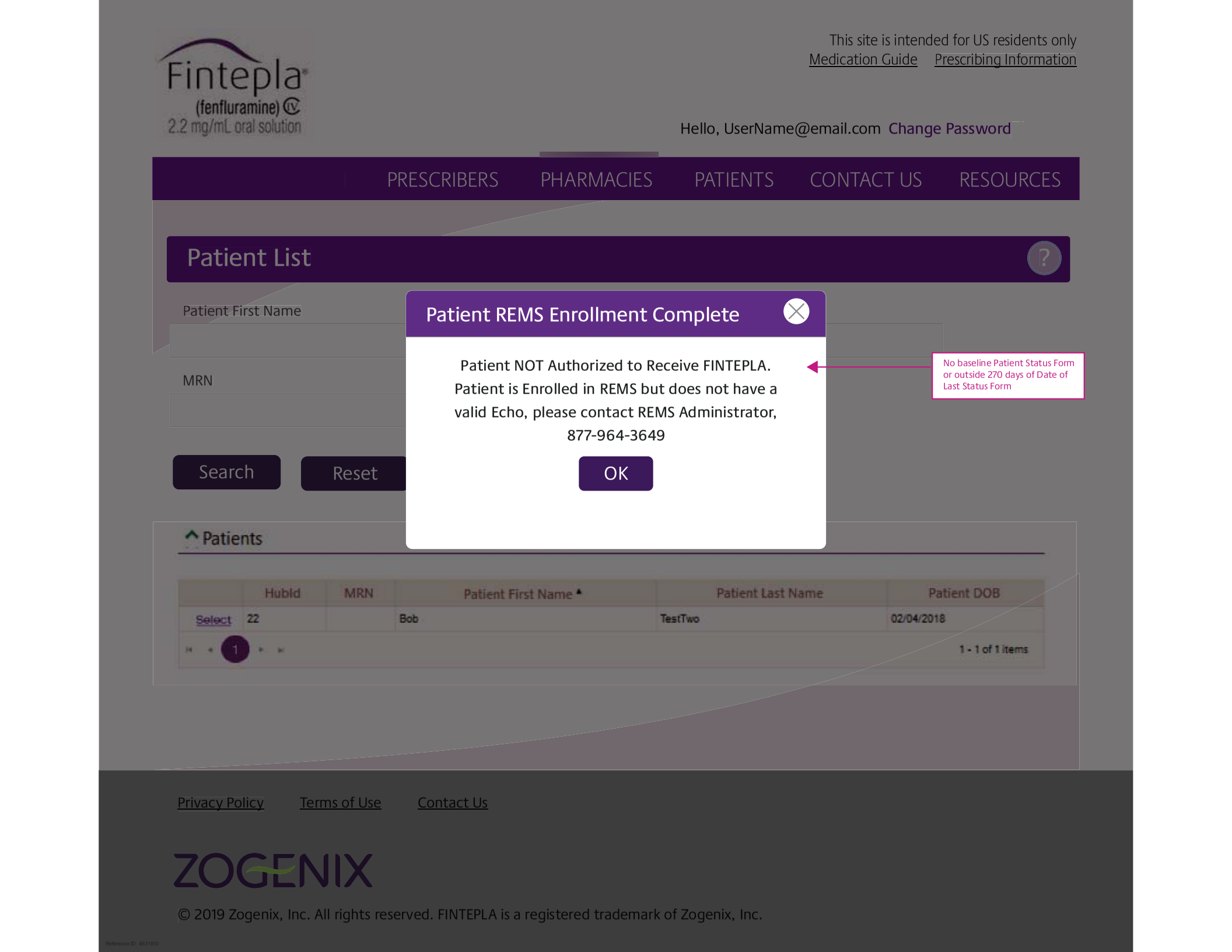
Option would be:
Patient Authorized or
Patient Authorized-Warning

Authorization Number 17890659

A unique authorization number will be generated for each authorization to dispense, which FINTEPLA REMS will record in the patient's file. The pharmacy is not required to maintain record of the authorization number.

Do you want to authorize another patient?

Yes No


Fintepla
(fenfluramine) CV
2.2 mg/mL oral solution
This site is intended for US residents only
Medication Guide
Prescribing Information
Hello, UserName@email.com
Change Password
PRESCRIBERS
PHARMACIES
PATIENTS
CONTACT US
RESOURCES
Patient List
Patient First Name
MRN
Search
Reset
Patient REMS Enrollment Complete
Patient NOT Authorized to Receive FINTEPLA. Patient is Enrolled in REMS but does not have a valid Echo, please contact REMS Administrator, 877-964-3649
OK
No baseline Patient Status Form or outside 270 days of Date of Last Status Form
Patients
HubId
MRN
Patient First Name
Patient Last Name
Patient DOB
Select
22
Bob
TestTwo
02/04/2018
1 - 1 of 1 items
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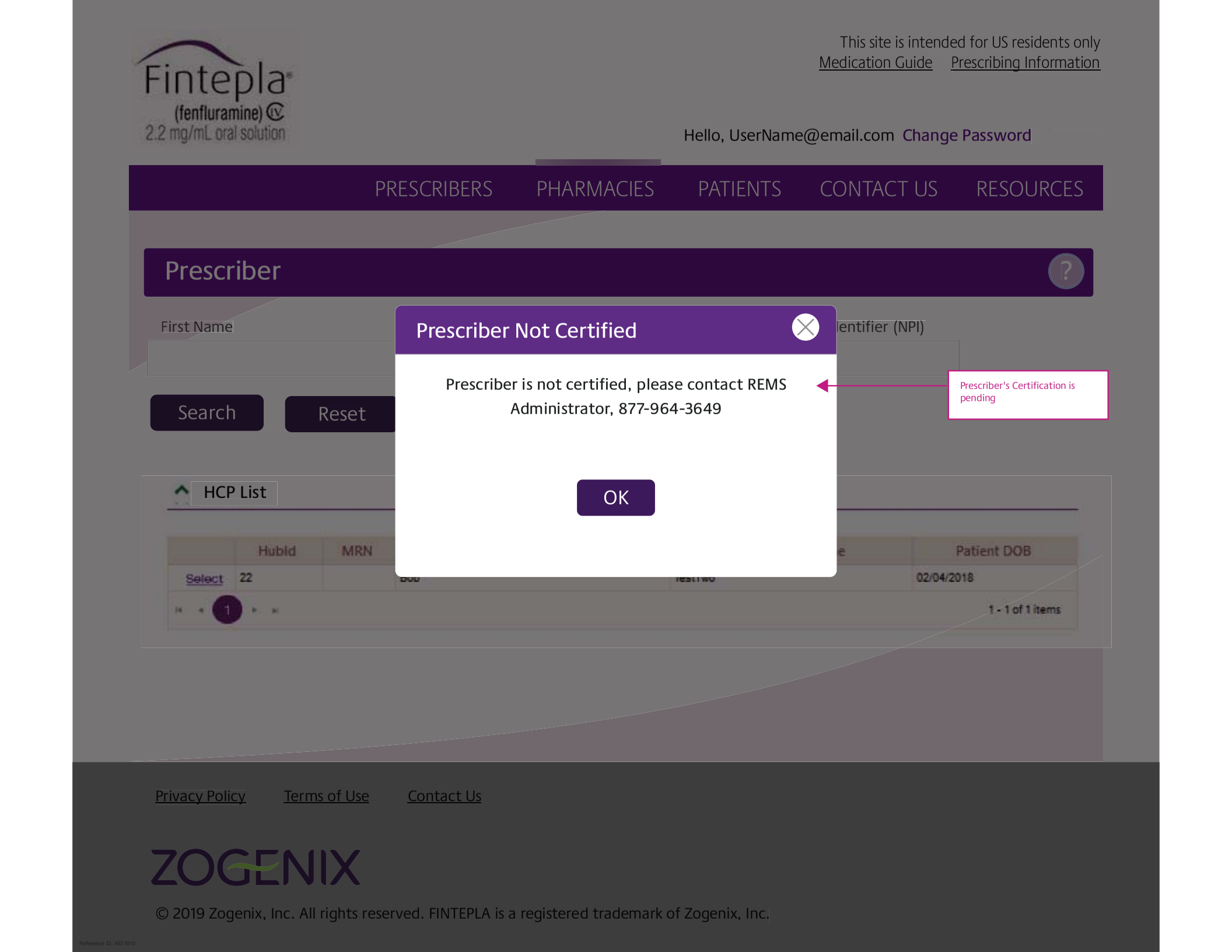
Fintepla
(fenfluramine) CIV
2.2 mg/mL oral solution
This site is intended for US residents only
Medication Guide
Prescribing Information
Hello, UserName@email.com
Change Password
PRESCRIBERS
PHARMACIES
PATIENTS
CONTACT US
RESOURCES
Prescriber
First Name
entifier (NPI)
Search
Reset
Prescriber Not Certified
Prescriber is not certified, please contact REMS Administrator, 877-964-3649
OK
Prescriber's Certification is pending
HCP List
Hubld
MRN
Patient DOB
Select
22
02/04/2018
1 - 1 of 1 items
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Terms of Use
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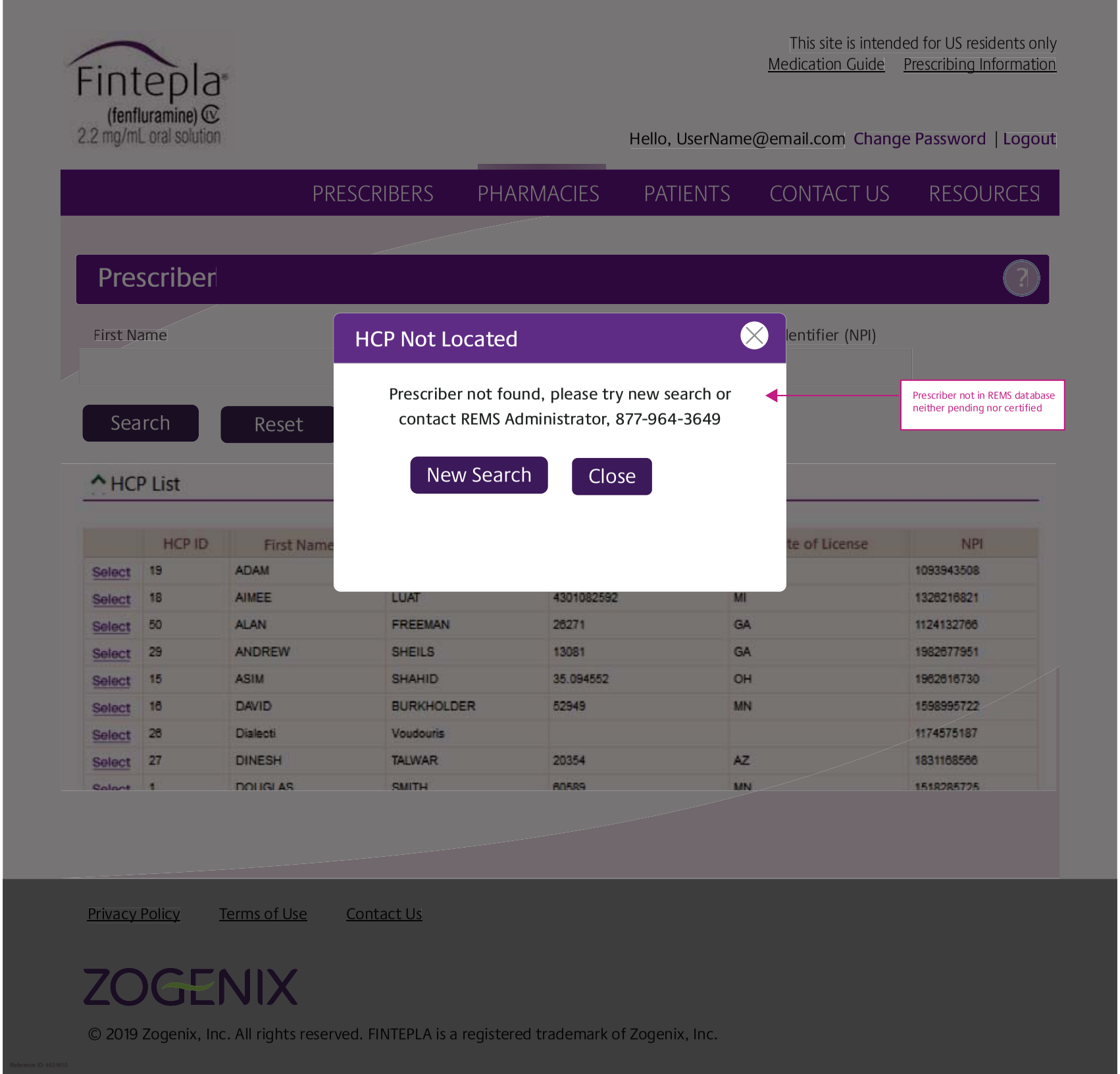
Fintepla
(fenfluramine) CV
2.2 mg/mL oral solution
This site is intended for US residents only
Medication Guide
Prescribing Information
Hello, UserName@email.com Change Password | Logout
PRESCRIBERS
PHARMACIES
PATIENTS
CONTACT US
RESOURCES
Prescriber
First Name
lentifier (NPI)
Search
Reset
HCP List
HCP Not Located
Prescriber not found, please try new search or contact REMS Administrator, 877-964-3649
New Search
Close
Prescriber not in REMS database neither pending nor certified
HCP ID
First Name
te of License
NPI
Select 19 ADAM 1093943508
Select 18 AIMEE LUAT 4301082592 MI 1326216821
Select 50 ALAN FREEMAN 26271 GA 1124132766
Select 29 ANDREW SHEILS 13081 GA 1982677951
Select 15 ASIM SHAHID 35.094552 OH 1962616730
Select 16 DAVID BURKHOLDER 52949 MN 1598995722
Select 26 Dialecti Voudouris 1174575187
Select 27 DINESH TALWAR 20354 AZ 1831168566
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Patient List

Patient First Name

MRN

Search Reset

Patient REMS Enrolled Valid Echo

Patient Authorized to Receive FINTEPLA.
Patient has a valid Echo to obtain an
Authorization number for the dispense

OK

Patients

	HubId	MRN	Patient First Name ▲	Patient Last Name	Patient DOB
Select	22		Bob	TestTwo	02/04/2018

1 - 1 of 1 items

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PRESCRIBERS PHARMACIES PATIENTS CONTACT US RESOURCES

Patient List

Patient First Name

MRN

Search Reset

Patient Not Located

Patient not found, please try new search or contact REMS Administrator, 877-964-3649

New Search Close

Patient is not in the REMS database nor pending enrollment.

Patients

	HubId	MRN	Patient First Name	Patient Last Name	Patient DOB
Select	19		Alice	Test-One	01/02/2018
Select	14		Amy	Test-Nineteen	02/02/2017
Select	18		Ann	Gatestone	02/15/2019
Select	22		Bob	TestTwo	02/04/2018
Select	17		Catherine	Test-Twentyfive	03/10/2013

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PATIENTS

What is FINTEPLA?

FINTEPLA 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 **R**isk **E**valuation and **M**itigation **S**trategy (**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 the 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

FINTEPLA ECHO Monitoring Timeline

It is important that you read the Medication Guide that comes with your medicine for more information about FINTEPLA. 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 other 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).

CONTACT US

For FINTEPLA REMS Information contact:

FINTEPLA REMS
1710 Shelby Oaks Drive North Suite #3
Memphis, TN 38134

Phone: 877-964-3649
Fax: 833-568-6198
www.FinteplaREMS.com

Reference ID: 4631810

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

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RESOURCES

Prescribers

Prescriber Training
REMS Program Overview
Prescriber Knowledge Assessment
Prescriber Enrollment Form
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Patient Status Form
Cardiovascular Adverse Event Reporting Form
Letter for Healthcare Providers
Prescribing Information

Pharmacies

Pharmacy Guide
Outpatient Enrollment Form
Inpatient Enrollment Form
REMS Program Overview

Patients

Patient Guide

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/s/

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