# 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:

o pr	escribe FINTEPLA must:
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.
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	1.	Healthcare	providers	who	prescribe FINTEPLA must:
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Before treat	tment	initia	ation
(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 prescrib	ed FINTEPLA:
During treatment: Every 6 months	<ol> <li>Receive counseling from the prescriber on the need to get an echocardiogram every 6 months during treatment using the Patient Guide.</li> </ol>
	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 1. Designate an authorized representative to carry out the dispense 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 6. Have the new authorized representative enroll in the REMS dispense 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.

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

4. Inpatient pharmacies th	nat dispense FINTEPLA must:
	<ol> <li>Have the authorized representative enroll in the REMS by completing the Inpatient Pharmacy Enrollment Form and submitting it to the REMS.</li> </ol>
	4. Train all relevant staff involved in dispensing FINTEPLA on the REMS Program requirements using the Pharmacy Guide.
Before dispensing	<ol> <li>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.</li> </ol>
	<ol> <li>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.</li> </ol>
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.
	<ol> <li>Maintain records that all processes and procedures are in place and being followed.</li> </ol>
	<ol> <li>Maintain records that document staff's completion of REMS training.</li> </ol>
	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	<ol> <li>Establish processes and procedures to ensure that the drug is distributed only to certified pharmacies.</li> </ol>
	<ol><li>Train all relevant staff involved in distributing FINTEPLA on the REMS requirements.</li></ol>
At all times	3. Distribute FINTEPLA only to certified pharmacies.
	4. Maintain records of all distributions.
	<ol><li>Comply with audits carried out by Zogenix, Inc. or a third party acting on behalf of Zogenix, Inc. to ensure that all</li></ol>

# 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.

processes and procedures are in place and are being followed.

# 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
Taruet	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.
- 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:

- 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: S	SUBMIT	
OUTPATIENT PHARMACY INFORMATION	I				* indicates required field.
Pharmacy Name*:		Pharmacy Address Line 1	*:		•
		I			
AUTHORIZED REPRESENTATIVE INFOR	MATION			T	* indicates required field.
First Name*:		Phone*:		Fax:	
AUTHORIZED PHARMACY REPRESENTA	ATIVE AGREEMENT				
I am the Authorized Representative designated by my	Outpatient Pharmacy to coo	rdinate the activities of the F	REMS.		
By completing, signing, and submitting this form, on be	half of myself and my Outpa	atient Pharmacy, <b>I attest tha</b>	at:		
I have reviewed the <i>Pharmacy Guide</i> and the <i>I</i>	REMS Program Overview				
I am enrolling in the REMS					
I agree to train all relevant staff involved in disp	ensing FINTEPLA on the RI	EMS requirements using the	e <i>Pharmacy</i> G	uide	
<ul> <li>I will ensure that, before dispensing, all pharms the prescriber is certified and the patient is enr</li> </ul>	-		ion by contact	ing the FINTEF	LA REMS to verify that
I agree to ensure that all pharmacy staff do not	distribute, transfer, loan, or	sell FINTEPLA, except to ce	ertified pharma	acies	
I will maintain records of dispensing informatio	n				
I will maintain records documenting staff's com	pletion of REMS training				
I will maintain records that all REMS processes	s and procedures are in plac	e and being followed			
<ul> <li>I will ensure that all pharmacy staff comply with processes and procedures are in place and are</li> </ul>		nix, Inc. or a third party actin	ng on behalf of	Zogenix, Inc. t	o ensure that all
If the authorized representative changes, this paramacy Enrollment Form	oharmacy will have the new a	authorized representative er	nroll in the REI	MS by complet	ing the <i>Outpatient</i>





STEP 1: REVIEW	STEP 2: COMPLETE AN	ID SIGN	STEP 3: SUB	MIT	
INPATIENT PHARMACY INFORMATION				* indicates required fi	eld.
Pharmacy Name*:	Pha	armacy Address Line 1	*.		
	I				
AUTHORIZED REPRESENTATIVE INFO	RMATION				
First Name*:	Pho	one*:	Fax	X:	
AUTHORIZED PHARMACY REPRESENT	TATIVE AGREEMENT				
I am the Authorized Representative designated by m		the activities of the R	EMS.		
By completing, signing, and submitting this form, on					
I have reviewed the Pharmacy Guide and the	e REMS Program Overview				
I am enrolling in the REMS					
I agree to train all relevant staff involved in dis	spensing FINTEPLA on the REMS	requirements using th	e Pharmacy Guide		
For patients initiating treatment: Before dispersional     FINTEPLA REMS to verify that the prescribe					
For patients continuing treatment: Before dis to verify that the patient is under the care of a					
I will not dispense more than 15 days' supply	, , ,	The common and addition	511204 10 1000110 1 11		
I agree to ensure that all pharmacy staff do n	ot distribute, transfer, loan, or sell I	FINTEPLA			
I will maintain records of dispensing informat	ion				
I will maintain records documenting staff's co	ompletion of REMS training				
I will maintain records that all REMS process	es and procedures are in place an	d being followed			
<ul> <li>I will ensure that all pharmacy staff comply w processes and procedures are in place and a</li> </ul>		nc. or a third party acti	ng on behalf of Zoge	enix, Inc. to ensure that all	
If the authorized representative changes, this     Inpatient Pharmacy Enrollment Form	s pharmacy will have the new autho	orized representative e	enroll in the REMS n	ny completing the	







# **Prescriber Training**

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

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# 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.

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# **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)

- fenfluramine (the active ingredient in FINTEPLA), and valvular heart disease and pulmonary arterial There is an association between serotonergic drugs with 5-HT2B receptor agonist activity, including hypertension
- regurgitation is considered a physiologic or normal finding in the absence of valvular abnormalities aortic or mitral regurgitation compared with 0-6% of patients taking placebo. Trace aortic or mitral treatment of Dravet syndrome, 0.4-16% of patients taking FINTEPLA were found to have trace 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

# **FINTEPLA REMS Overview**

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

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# What Is the FINTEPLA REMS?

- The FINTEPLA REMS (Risk Evaluation and Mitigation Strategy) 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

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# 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

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

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# **FINTEPLA REMS**



# 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.

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



# 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?

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

<sup>|</sup> | CV, cardiovascular; ECHO, echocardiogram; PAH, pulmonary arterial hypertension; VHD, valvular heart disease.

Phone:1-877-964-3649 • www.FinteplaREMS.com

Reference ID: 4631810

• Fax: 1-833-568-6198

Phone: 1-877-964-3649

# www.FinteplaREMS.com

# Fax: 1-833-568-6198

# What Are the Requirements of the FINTEPLA REMS?

Ŗ.	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 for 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 abon malities 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 FINTEDLA     Enroll in the REMS with your healthcare provider     Get an ECHO to check your heart     Before you start FINTEDLA     Every 6 months to continue treatment     Once 3 to 6 months after     stopping treatment     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	





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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	A11 C (1.1)	" PENO
Answer the following questions by selecting the single best answer. You must ans	wer ALL questions correctly to become certified if	1 the REMS.





# **FINTEPLA REMS**



# 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.

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# 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 lungs. Your healthcare provider will check your heart valves and lung artery pressures with a test called an echocardiogram (ECHO), which with their heart valves or high blood pressure in the arteries of their

is an ultrasound picture of the heart. If your ECHO shows any problems with your heart alves 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?

US Food and Drug Administration (FDA) can require for certain medicines with serious make sure the benefits of using the drug are more than the risks. FDA must approve A Risk Evaluation and Mitigation Strategy (REMS) is a drug safety program that the safety concerns. Drug companies and healthcare providers must take extra steps to these steps as part of the REMS.



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Fax: 1-833-568-6198 •

# Why does FINTEPLA have a REMS?



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

# 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
- 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 An ECHO can identify heart valve problems or high blood pressure in the arteries and at regular intervals while on the medicine

# How do I receive FINTEPLA?

- 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 After you and your healthcare provider have discussed your ECHO results and
- 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?

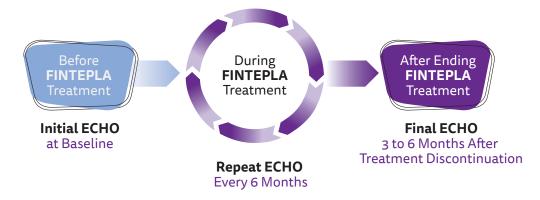
You will have an ECHO every 6 months as long as you are taking FINTEPLA

# 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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# 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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Reference ID: 4631810

# **FINTEPLA REMS**



# 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.

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# 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

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. disease and pulmonary arterial hypertension. In clinical trials of FINTEPLA for the treatment of Dravet syndrome, no cases of valvular heart serotonergic drugs with 5-HT2B receptor agonist activity including fenfluramine (the active ingredient in FINTEPLA), and valvular heart disease or pulmonary hypertension were reported. Across clinical trials of FINTEPLA for the treatment of Dravet syndrome, 0.4-1.6% of Valvular heart disease and pulmonary arterial hypertension have been associated with fenfluramine. There is an association between

# 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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Fax: 1-833-568-6198

www.FinteplaREMS.com

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Phone: 1-877-964-3649

Reference ID: 4631810

# 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
- 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 Upon notice from the REMS, ALL pharmacies must provide complete and accurate requested REMS data such as patient, prescriber,

# How Does a Pharmacy Become Certified in the FINTEPLA REMS?

In order to become	-	<ol> <li>Designate an authorized representative to carry out the certification process and oversee implementation</li> </ol>	_
certified, the		and compliance with the REMS requirements on behalf of the pharmacy	
pharmacy must	6	2. Have the authorized representative review this Pharmacy Guide and the REMS Program Overview	
	κ'n	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	<del>-</del> -	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	6	2. Have the new authorized representative enroll in the REMS by completing the Outpatient Pharmacy
certification to		Enrollment Form if the authorized representative changes
dispense		
Atalltimes	κ'n	3. Not distribute, transfer, loan, or sell FINTEPLA, except to certified pharmacies
	4	4. Maintain records that all processes and procedures are in place and being followed
	ιÿ	. Maintain records documenting staff's completion of REMS training
	9	. Maintain records of dispensing information including patient, prescriber, prescription, and dispensing data
	7	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

# What Are the Responsibilities of Inpatient Pharmacies?

Before dispensing	<ol> <li>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</li> </ol>
	<ol> <li>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</li> </ol>
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 <i>Inpatient Pharmacy Enrollment Form</i> 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
	<ol><li>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</li></ol>
	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.

<u>Authorized:</u> 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	k.	
				-
PRESCRIBER INFORMA	TION	1		* indicates required field.
First Name*:		Address Line 1	·.	
FINTEPLA DOSING INFO	ORMATION			* indicates required field.
Current dose of FINTEPLA:	mg/kg/day	Total	mg/day	
	, , ,	l .	<u> </u>	
<b>ECHOCARDIOGRAM RE</b>	SULTS			* indicates required field.
Date of echocardiogram (MM/D	)D/YYYY)*: / /			
		gurgitation (check only 1 box per r		
	T T	o severe," check the more severe		
Valve	Absent/Trace	Mild	Moderate	Severe
Authorization for Treatment				
Authorization for freatment				
If this nationt is not authorized t	to receive FINTEDI A Inlease pro	vide the reason(s) (select all that	annly)*	





PATIENT INFORMATION			* indicates required field.
First Name*:		Address Line 1*:	
PRESCRIBER INFORMATION			* indicates required field.
First Name*:		Address Line 1*:	
CARDIOVASCULAR ADVERSE			* indicates required field.
Cardiac findings on echocardiogram (sele	ect all that apply)*:		
Valvular heart disease (VHD)			
_			







### [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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**PHARMACIES** 

**PATIENTS** 

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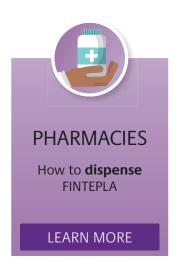
### What is the FINTEPLA REMS (Risk Evaluation and Mitigation Strategy)?

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 Druq 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.







### 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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### **Prescriber Requirements**

### How do I become certified to prescribe FINTEPLA?

- I. 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:
  - <u>Online</u>

  - By Mail



- · 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 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

### **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
  - 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
- 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.
- Report treatment discontinuation or transfer of care to the REMS.

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### **FINTEPLA REMS Prescriber Enrollment Form**

### FOR PRESCRIBERS

- 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

First 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*: Primary Contact at Office Last Name:  Primary Contact Title: Adult Neurology Pediatric Epileptology Pediatric Epileptology (If yes, please complete the following 2 fields)  Preferred Method of Communication: Email Phone Fax Primary Contact Direct Phone Number:	
Degree*: MD DO NP PA Other (please specify)  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*: Primary Contact at Office Last Name: Primary Contact at Office Last Name:  Primary Contact Title: Adult Neurology Pediatric Epileptology 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)  Preferred Method of Communication: Email Phone Fax Primary Contact Direct Phone Number:	
Prescriber's DEA Number*:  City*: State*: ZIP Code*  National Provider Identifier (NPI)*:  Practice/Facility Phone*:  State License Number:  Prescriber Email*:  Primary Contact at Office First Name:  Primary Contact at Office Last Name:  Primary Contact Title:  Adult Epileptology Pediatric Epileptology Pediatric Epileptology Primary Contact phone and fax numbers different from practice/facility phone and fax numbers?  (If yes, please complete the following 2 fields)  Preferred Method of Communication:  Email Phone Fax Primary Contact Direct Phone Number:	
Prescriber's DEA Number*:  National Provider Identifier (NPI)*:  Practice/Facility Phone*:  State License Number:  Prescriber Email*:  Primary Contact at Office First Name:  Primary Contact at Office Last Name:  Primary Contact Title:  Adult Epileptology  Pediatric Epileptology  Pediatric Epileptology  Preferred Method of Communication:  Email  Phone  Fax  Primary Contact Direct Phone Number:	
State License Number:  Prescriber Email*:  Primary Contact at Office First Name:  Primary Contact at Office Last Name:  Primary Contact at Office Last Name:  Primary Contact at Office Last Name:  Primary Contact Title:  Adult Epileptology  Pediatric Epileptology  Are primary contact phone and fax numbers different No from practice/facility phone and fax numbers? (If yes, please complete the following 2 fields)  Preferred Method of Communication:  Email Phone Fax  Primary Contact Direct Phone Number:	*:
Prescriber Email*:  Specialty*:  Adult Neurology  Pediatric Neurology  Pediatric Epileptology  Adult Epileptology  Pediatric Epileptology  Pediatric Epileptology  Are primary Contact phone and fax numbers different from practice/facility phone and fax numbers?  (If yes, please complete the following 2 fields)  Preferred Method of Communication:  Email Phone Fax  Primary Contact at Office Last Name:  Primary Contact Title:  Are primary contact phone and fax numbers?  (If yes, please complete the following 2 fields)	
Specialty*:  Adult Neurology Pediatric Neurology 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)  Preferred Method of Communication:  Email Phone Fax  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)	
Adult Neurology Pediatric Neurology Primary Contact Title:  Adult Epileptology Pediatric Epileptology Adult Epileptology 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)  Preferred Method of Communication:  Email Phone Fax Primary Contact Direct Phone Number:	
Primary Contact Title:  Adult Epileptology  Pediatric Epileptology  Are primary contact phone and fax numbers different from practice/facility phone and fax numbers?  (If yes, please complete the following 2 fields)  Preferred Method of Communication:  Email Phone Fax Primary Contact Direct Phone Number:	
Other (please specify)  Preferred Method of Communication:  Email Phone Fax Primary Contact phone and fax numbers different from practice/facility phone and fax numbers? (If yes, please complete the following 2 fields)  Primary Contact Direct Phone Number:	
Preferred Method of Communication: Email Phone Fax Primary Contact Direct Phone Number:	Yes
Primary Contact Email: Primary Contact Fax Number:	
PRESCRIBER AGREEMENT  Purpose to a comply with the following DEMS requirements:	
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	
<ul> <li>Counsel the patient on the risks of valvular heart disease and pulmonary arterial hypertension, including how to recognize and respond to symptoms of valvular heart disease and pulmonary arterial hypertension, and the need for cardiac monitoring via echocardiogram at base initiation), every 6 months during treatment, and once 3 to 6 months after treatment discontinuation using the Patient Guide</li> </ul>	
Enroll the patient by completing and submitting the Patient Enrollment Form to the REMS	
<ul> <li>Assess the patient's cardiovascular status and the appropriateness of initiating treatment by obtaining an echocardiogram. Document and and authorization for treatment to the REMS using the Patient Status Form</li> </ul>	I submit the results
During treatment, every 6 months, I will:	
<ul> <li>Counsel the patient on the need for cardiac monitoring via echocardiogram every 6 months during treatment and once 3 to 6 months after discontinuation using the Patient Guide</li> </ul>	· treatment
<ul> <li>Assess the patient's cardiovascular status and the appropriateness of continuing treatment by obtaining an echocardiogram. Document ar results and appropriateness of continued treatment to the REMS using the Patient Status Form</li> </ul>	nd submit the
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's cardiovascular status by obtaining an echocardiogram.	ent 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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User Name Password

Forgot password?

Login

New Prescriber User? Click <u>here</u> to Create Login New Pharmacy User? Click here to Create 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 \*

Prescriber Email \*

Re-enter Prescriber Email \*

I'm not a robot

Create Login

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This allows the prescriber to access online forms after login to the website. RESOURCES Cardiovascular Adverse Event Reporting Form CONTACT US Letter for Healthcare Providers Prescribing Information Patient Status Form START **PATIENTS PHARMACIES** Prescriber Knowledge Assessment **REMS Prescriber Knowledge Assessment Certification** Prescriber Enrollment Form REMS Program Overview Patient Enrollment Form Prescriber Training Patient Guide **PRESCRIBERS Documents Tools** 

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### **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

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PHARMACIES 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. O True O False Question 2: In order to receive FINTEPLA, patients must enroll in REMS. O True O False Question 3: FINTEPLA is indicated for the treatment of seizures associated with Dravet syndrome in patients 2 years of age and O True O False Question 4: The signs and symptoms for valvular heart disease and pulmonary arterial hypertension may include: Shortness of breath Fatique Dizziness or fainting Swelling of ankles and feet O Rapid heartbeat O 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. O 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. O 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. O True ○ False Question 8: Only pharmacies certified in the REMS may dispense FINTEPLA to patients. O True False Question 9: An echocardiogram can identify evidence of valvular heart disease or pulmonary arterial hypertension prior to a patient becoming symptomatic

Click to Submit and continue to Certification

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O True O False



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### **PRESCRIBERS**

### FINTEPLA REMS Prescriber Knowledge Assessment Results

Prescribers who successfully complete the Prescriber Knowledge Assessment will receive:

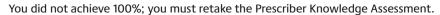
You have successfully completed the Prescriber Knowledge Assessment.

 $You \ must \ complete \ the \ Prescriber \ Enrollment \ and \ submit \ to \ the \ REMS \ before \ prescribing \ FINTEPLA.$ 

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 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

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PRESCRIBERS PHARMACIES PATIENTS CONTACT US RESOURCES



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By fax to 1-833-568-6198     By mail to 1710 N Shelby Oaks Dr., Ste 3, M		
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ZOGENIX

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### 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 FINTEPA. It ANO 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

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

		fields below. Required fie	lds are denoted by				
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Fintepla\*
(fentluramine) @
2.2 mg/mL oral solution



### 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 1-833-566-6198, or via mall to 1710 N Shelby Oals 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 Friding between 7 AM-7 PM. Central Time.

First Name *	Last Name *			RI	EMS ID *			
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street Address, line I								
Street Address, line 2								
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rescriber Information								
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### **Create Login**

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### **Outpatient Pharmacy Requirements**

### How do I become certified to dispense FINTEPLA?

- 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.
- Have the authorized representative enroll in the REMS by completing the Outpatient Pharmacy Enrollment Form and submitting it to the REMS.
  - Online
  - Fav
- 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

 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

 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?

- Designate an authorized representative to carry out the certification process and oversee implementation and compliance with the REMS requirements on behalf of the pharmacy.
- ${\bf 2. \ \ Have \ the \ authorized \ representative \ review \ the \ Pharmacy \ Guide \ and \ REMS \ Program \ Overview.}$
- 3. Have the authorized representative enroll in the REMS by completing the Inpatient Pharmacy Enrollment Form and submitting it to the REMS.
- Online
- <u>Fax</u>
- 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

- 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

- 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.

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### **OUTPATIENT PHARMACY**

### Outpatient Pharmacy Enrollment Form

STEP 1: REVIEW		
Designate an Authorized Representative.     Authorized Representative review the Pha	rmacy Guide and REMS Program Overview	
STEP 2: COMPLETE AND SIGN	,	
	olete and sign this Outpatient Pharmacy Enrollment the new Authorized Representative must complete	
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, Sui	te 3, Memphis, TN 38134	
o submit this form, please complete all requi	red fields below. Required fields are denoted by"	•••.
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### INPATIENT PHARMAC

### Inpatient Pharmacy Enrollment Form

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<ul> <li>If the Authorized Representative changes, Form.</li> </ul>	the new Authorized Representative	must complete and	sign an new Inpatient Pharmacy Enrollme	ent
TEP 3: SUBMIT				
Submit this form either:     Online at www.FinteplaREMS.com or				
<ul> <li>Via fax to 1-833-568-6198 or</li> <li>Via mail to 1710 N Shelby Oaks Dr, Suit</li> </ul>	e 3, Memphis, TN 38134			
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completing, signing, and submitting this form  I have reviewed the Pharmacy Guide and RE	n on behalf of myself and my inpa			
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**Tools** 

Verify Prescriber Certification & Patient Enrollment

VERIFY

**Authorization Number** Obtain Dispense

START

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RESOURCES CONTACT US National Provider Identifier (NPI) **PATIENTS PHARMACIES** Last Name **PRESCRIBERS Prescriber** First Name

## ◆ Prescriber List

Reset

Search

	HCP ID	First Name ▲	Last Name	State License No	State of License	IdN
Select	19	ADAM	NUMIS	A116439	CA	1093943508
Select	18	AIMEE	LUAT	4301082592	MI	1326216821
Select	50	ALAN	FREEMAN	26271	GA	1124132788
Select	29	ANDREW	SHEILS	13081	GA	1982877951
Select	15	ASIM	SHAHID	35.094552	Н	1962616730
Select	16	DAVID	BURKHOLDER	52949	MN	1598995722
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RESOURCES CONTACT US **PATIENTS REMS ID PHARMACIES** Patient Last Name **PRESCRIBERS** DOB Reset Patient List Patient First Name Search → Patients MRN

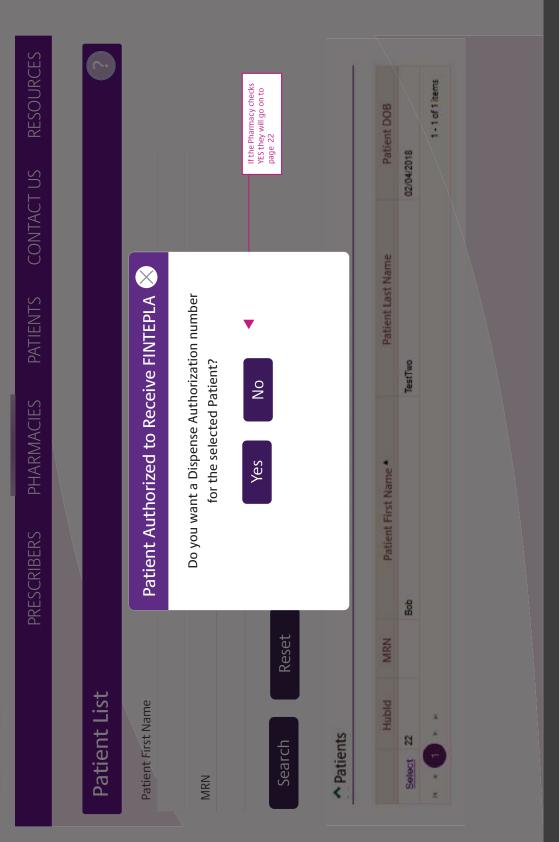
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Select	14		Amy	Test-Nineteen	02/02/2017
Select	18		Ann	Gatestone	02/15/2019
	22		Bob	TestTwo	02/04/2018
	17		Catherine	Test-Twentyfive	03/10/2013

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**C** 

# Dispense Authorization Number

### Back

# ◆ Patient and Provider Information

Patient First Name	Anee	Provider First Name THOMAS	THOMAS
Patient Last Name	ū	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: 
Authorization Number 17890659

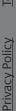
Option would be: Patient Authorized or Patient Authorized-Warning

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

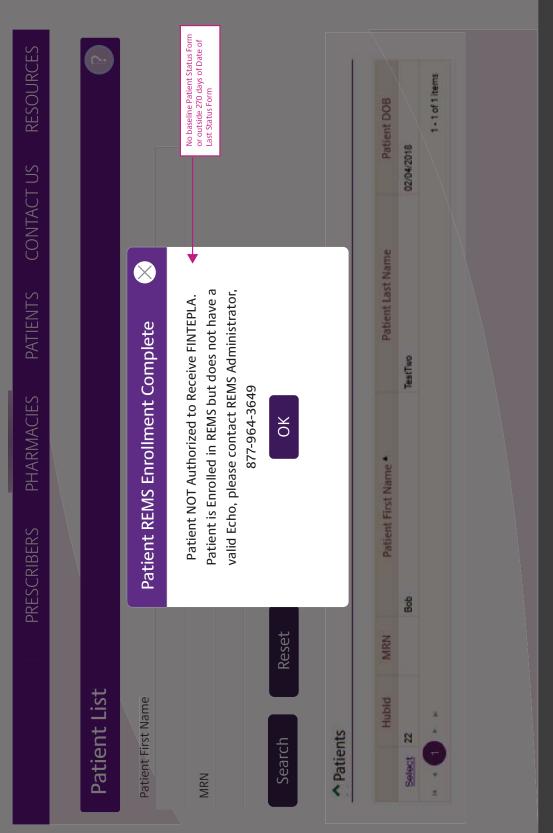


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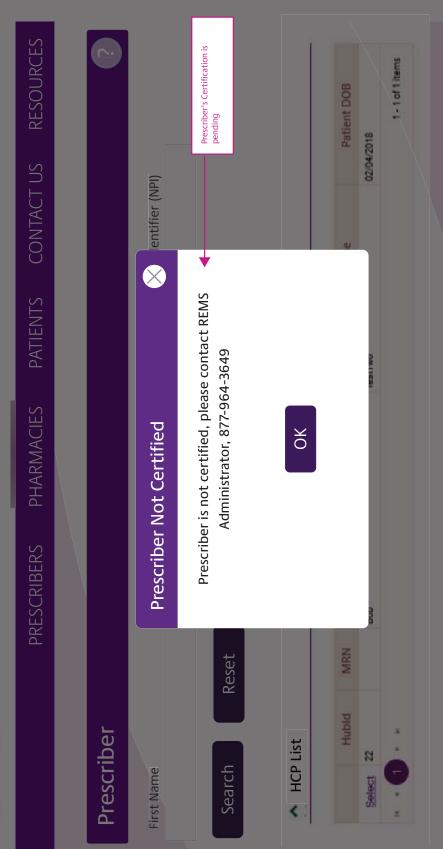


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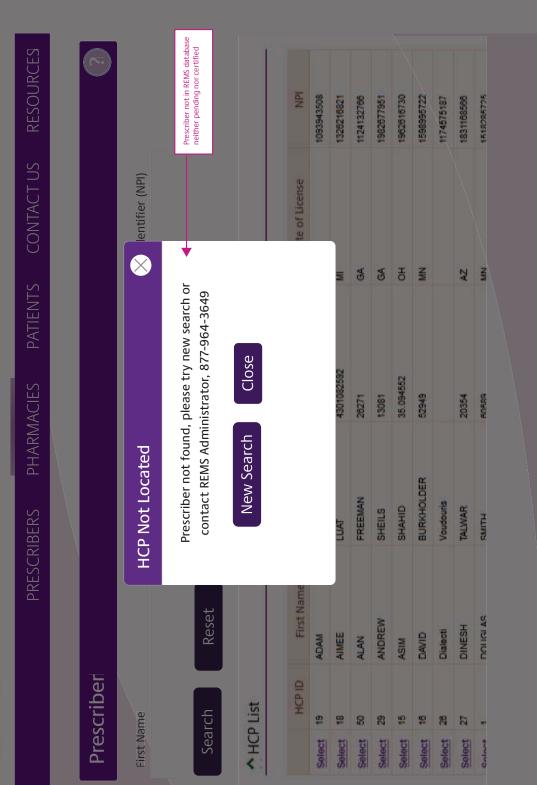


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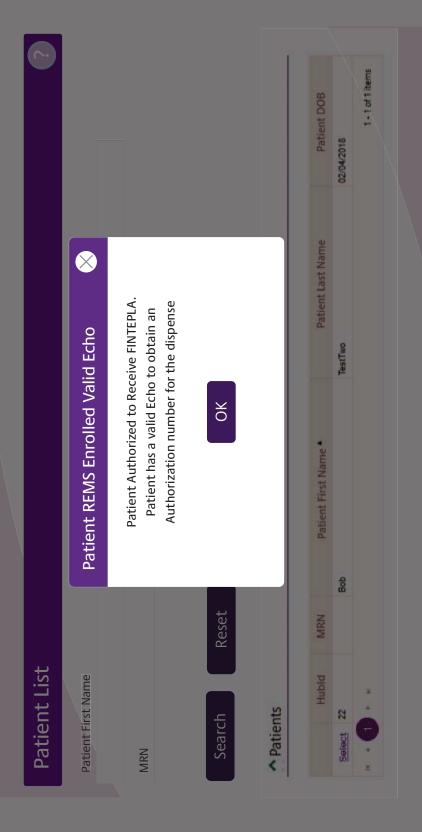
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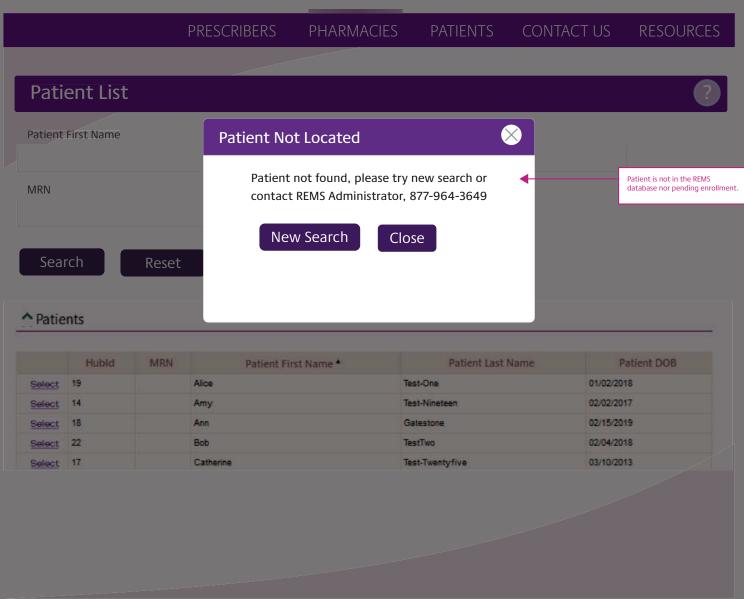
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### What is FINTEPLA?

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
- Fatique
- Chest pressure or pain
- · Swelling of ankles and feet
- · Dizziness or fainting spell

### What is the FINTEPLA REMS?

A Risk Evaluation and Mitigation Strategy (REMS) is a drug safety program that the US Food and Drug Administration (FDA). Can require for certain medicines with serious safety concerns. Drug companies and healthcare providers must take extra steps to make sure the benefits of using the drug are more than the risks. FDA must approve these steps as part of the REMS.

### Why does FINTEPLA have a REMS?

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

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

- · Review 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).

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## **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

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REMS Program Overview

Outpatient Enrollment Form Inpatient Enrollment Form REMS Program Overview

Pharmacy Guide **Pharmacies** 

Prescriber Knowledge Assessment

Prescriber Enrollment Form

Patient Guide

Patient Enrollment Form Patient Status Form

Cardiovascular Adverse Event Reporting Form

Letter for Healthcare Providers

Prescribing Information

## **Patients**

Patient Guide

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This is a representation of an electronic record that was signed
electronically. Following this are manifestations of any and all
electronic signatures for this electronic record.

/s/

NICHOLAS A KOZAUER 06/25/2020 06:43:49 PM