

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



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.

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*: <input type="checkbox"/> MD <input type="checkbox"/> DO <input type="checkbox"/> NP <input type="checkbox"/> PA <input type="checkbox"/> 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*: <input type="checkbox"/> Adult Neurology <input type="checkbox"/> Pediatric Neurology <input type="checkbox"/> Adult Epileptology <input type="checkbox"/> Pediatric Epileptology <input type="checkbox"/> 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 <input type="checkbox"/> Yes <input type="checkbox"/>		
Preferred Method of Communication: <input type="checkbox"/> Email <input type="checkbox"/> Phone <input type="checkbox"/> 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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Phone: 1-877-964-3649 | www.FinteplaREMS.com | Fax: 1-833-568-6198

Fintepla[®]
(fenfluramine) 
2.2 mg/mL oral solution



This site is intended for US residents only
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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



Create Login



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Tools

[REMS Prescriber Knowledge Assessment Certification](#)

[START](#)

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

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](#)

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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](#)

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](#)



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](#)



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 authorization for 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 -

Signature *

SUBMIT

ZICR Part II requires a reason for signing the document



PRESCRIBERS

Patient Enrollment Form

Instructions
 Complete this form with your healthcare provider and submit:
 • Online at www.FinteplaEMS.com
 • By fax to 1-833-568-4198
 • 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 * 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 *

First Name * Last Name * REMS ID: *

Prescriber Email Prescriber Phone * Prescriber Fax *

Address Line 1 *

Address Line 2

City * State * ZIP Code *

Patient Agreement

I have received, read, and understand the Patient Guide that my healthcare provider has given me.
 Before my treatment begins:
 • 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 lightheaded 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

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

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

Prescriber Signature *



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 * 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 * 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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
MITRAL	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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

Signature *

SUBMIT



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 * Zip *

Prescriber Information

First Name * Last Name * REMS ID *

National Provider Identifier (NPI)*

Street Address, line 1*

Street Address, line 2

City * State * 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 Stripentol? * 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

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

Signature *

SUBMIT

LOGIN

PRESCRIBERS

PHARMACIES

PATIENTS

CONTACT US

RESOURCES



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



Create Login

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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 *
<input type="text"/>	<input type="text"/>	<input type="text"/>
Street Address, line 1 *		
<input type="text"/>		
Street Address, line 2		
<input type="text"/>		
City *	State *	Zip *
<input type="text"/>	- Select -	<input type="text"/>
Telephone Number *	Fax Number *	E-mail
<input type="text"/>	<input type="text"/>	<input type="text"/>

Authorized Representative Information

First Name *	Last Name *
<input type="text"/>	<input type="text"/>
Credentials *	<input type="radio"/> R.PH <input type="radio"/> PharmD <input type="radio"/> BCPS <input type="radio"/> Other (please specify) <input type="text"/>
Telephone Number *	Fax Number E-mail *
<input type="text"/>	<input type="text"/> <input type="text"/>
Preferred Method of Communication:	<input type="radio"/> Phone <input type="radio"/> Fax <input type="radio"/> 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 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.

Select Signing Reason

Signature *

SUBMIT



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 a 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



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PHARMACIES - HOME

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Prescriber



First Name

Last Name

National Provider Identifier (NPI)

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	SHELLS	13081	GA	1982677951
Select 15	ASIM	SHAHID	35.094552	OH	1962616730
Select 16	DAVID	BURKHOLDER	52949	MIN	159896722
Select 26	Dialecti	Voudouris			1174575187
Select 27	DINESH	TALWAR	20354	AZ	1831168566
Select 1	DOLIGIAS	SMITH	RD569	MIN	1518265725

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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	Galestone	02/15/2019
Select 22			Bob	TestTwo	02/04/2018
Select 17			Catherine	Test-Twentyfive	03/10/2013

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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

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

1 - 1 of 1 items

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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: **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](#)

Option would be:
 Patient Authorized
 Patient Authorized-Warning

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

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

1 - 1 of 1 items



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Prescriber

First Name

Search

Reset

HCP List

Prescriber Not Certified

Prescriber is not certified, please contact REMS Administrator, 877-964-3649

OK

Prescriber's Certification is pending

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Prescriber



First Name

Search

Reset

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 List

HCP ID	First Name	State of License	NPI
Select 19	ADAM		1093943508
Select 18	AIMEE	MI	1326216821
Select 50	ALAN	GA	1124132766
Select 29	ANDREW	GA	1982677951
Select 15	ASIM	OH	1962616730
Select 16	DAVID	MIN	159895722
Select 28	Dialecti	Voudouris	1174575187
Select 27	DINESH	TALWAR	1831168568
Select 1	DOLIGLAS	SMITH	1518285725

Patient List ?

Patient First Name

MRN

Patient REMS Enrolled Valid Echo

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

 Patients

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

1 of 1 items

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



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 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.

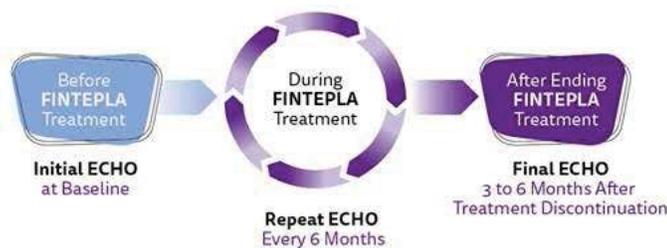
What do I need to do during the time I am on FINTEPLA?

- 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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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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/s/

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