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.

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 or (www.FDA.gov/medwatch)

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

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

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

PRESCRIBER INFORMATION
* indicates required field.

First Name*: Practice/Facility Name*:

Last Name*:

Address Line 1*:

Degree*: MD DO NP PA Other (please specify) Address Line 2:

Prescriber’s DEA Number*:

City*:

State*:

ZIP Code*:

National Provider Identifier (NPI)*:

Practice/Facility Phone*:

State License Number:

Practice/Facility Fax*:

Prescriber Email*:

Primary Contact at Office First Name:

Primary Contact at Office Last Name:

Primary Contact Title:

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)

Preferred Method of Communication: Email [ ] Phone [ ] Fax [ ]

Primary Contact Direct Phone Number: - -

Primary Contact Email: - -

Primary Contact Fax Number: - -

PRESCRIBER AGREEMENT

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

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

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

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

During treatment, every 6 months, I will:

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

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

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

At all times, I will:

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

Signature
Date
Login

User Name
Password

Forgot password?

Login

New Prescriber User? Click here to Create Login
New Pharmacy User? Click here to 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**: [Enter NPI Number]
  - [Lookup]
  - [Reset]

- **First Name**: [Enter First Name]  
- **Last Name**: [Enter Last Name]  
- **Prescriber Email**: [Enter Prescriber Email]
- **Re-enter Prescriber Email**: [Enter Re-enter Prescriber Email]

- [I'm not a robot]
Hello, UserName@email.com

Change Password | Logout

Tools

- REMS Prescriber Knowledge Assessment Certification

START

Documents

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

This site is intended for US residents only

Medication Guide | Prescribing Information

Reference ID: 4958939
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 and Lennox-Gastaut 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
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

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

- Review the FINTEPLA Prescribing Information, 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:

1. Give the patient a copy of the Patient Guide.
2. 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.
3. Enroll the patient by completing and submitting the Patient Enrollment Form to the REMS.
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.

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.
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 continued treatment to the REMS using the Patient Status Form.

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

1. Assess the patient's cardiovascular status by obtaining an echocardiogram. Document and submit the results to the REMS using the Patient Status Form.
2. 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.

Primary Contact at Office

First Name * Last Name * Title *

Preferred method of communication: E-mail Phone Fax

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

Prescriber Agreement

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

- Review the FINTEPLA Prescribing Information, 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 as a patient, I will:

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. 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 continued treatment to the REMS using the Patient Status Form.
3. 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.

Select Signing Reason *

- Select -

Signature *
Patient Enrollment Form

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

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

Patient Information

First Name * Last Name *
State of Birth (MM/DD/YYYY) *
Gender: * Male Female Neutral Prefer not to say
Race: * Black or African American White Other (please specify)
Name of Legal Guardian *
Legal Guardian Relationship *
Legal Guardian Phone *
Legal Guardian Email *
Street Address, line 1 *
Street Address, line 2
City * State * Zip *
Home Telephone *
Work Telephone *
Date of Birth (MM/DD/YYYY) *

Prescriber Information

First Name * Last Name *
Physician's License (NPI) Number *
Prescriber Fax *
RSME ID: *
Prescriber Email *
Address Line 2 *
Address Line 1 *
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 an echocardiogram (ECHO) to check my heart.
At all times:
- I will let all my healthcare providers know that I am taking FINTEPLA.
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.

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.

SUBMIT
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 abnormality or new abnormality via echocardiogram
- Valvular heart disease (VHD) as indicated by mild or greater aortic regurgitation or moderate or greater mitral regurgitation, with additional characteristics of VHD (e.g., valve thickening or restrictive valve motion).
- Pulmonary arterial hypertension (PAH) as indicated by elevated right heart/pulmonary artery pressure (PASP > 35 mm 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.

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

Patient Information

- First Name *
- Last Name *
- REMS ID
- Street Address, line 1 *
- Street Address, line 2
- City * State *
- Zip *
- Date of Birth (MM/DD/YYYY) *

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: Start Date: End Date:

Echocardiogram Results

- Date of ECHO (MM/DD/YYYY) *

Regurgitation

- (check only 1 box per row)
- In echocardiogram, the term "minimal" or "trace" in this column means categorizations "trace" or less, "mild" or less, "moderate" or less, and "severe".

AORTIC
- Absent/Trace
- Mild
- Moderate
- Severe

MITRAL
- Absent/Trace
- Mild
- Moderate
- Severe

Elevated pulmonary arterial systolic pressure (PASP > 35 mm Hg): (select one)
- Yes
- No

Any valvular abnormality or new abnormality via echocardiogram (select one)
- Yes
- No

Any new abnormality on echocardiogram: (select one)
- 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):
- [ ] Other (please specify):

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

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.
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 asterisks (*).

**Pharmacy Information**

- **Pharmacy Name**: 
- **Pharmacy National Provider Information (NPI)**: 

**Authorized Representative Information**

- **First Name**: 
- **Last Name**: 
- **Email**: 
- **Confirm Email**: 

To complete the form, you must enter all required fields, including your name, email address, and pharmacy information. The system will also ask you to confirm your email address to ensure the accuracy of your submission.
Documents

Pharmacies
- Pharmacy Guide
- Outpatient Enrollment Form
- Inpatient Enrollment Form
- REMS Program Overview
- Prescribing Information
- Medication Guide
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 the 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:
  - 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 “*”.

**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 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 being followed.
- I will ensure that the pharmacy will have the new authorized representative enrol in the REMS by completing the Outpatient Pharmacy Enrollment Form.

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

**Pharmacy Name**

**Street Address, line 1**

**City**

**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**

Select Signing Reason

- [ ] Signature
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 *

City * State * Zip *

Telephone Number * Fax Number * E-mail *

Authorized Representative Information

First Name * Last Name *

Credentials *: R.Ph, PharmD, BCPS, Other (please specify)

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.
- Before dispensing, all pharmacy staff must obtain authorization to dispense each prescription by contacting the FINTEPLA REMS to verify that the prescriber is certified, and the patient is enrolled and authorized to receive FINTEPLA.
- 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.
### Prescriber List

<table>
<thead>
<tr>
<th>HCP ID</th>
<th>First Name</th>
<th>Last Name</th>
<th>State License No</th>
<th>State of License</th>
<th>NPI</th>
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<td>TALWAR</td>
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### Patient List

<table>
<thead>
<tr>
<th>HubId</th>
<th>MRN</th>
<th>Patient First Name</th>
<th>Patient Last Name</th>
<th>Patient DOB</th>
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<tr>
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<td>Test-One</td>
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<td>Amy</td>
<td>Test-Nineteen</td>
<td>02/02/2017</td>
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<td>Ann</td>
<td>Gatestone</td>
<td>02/15/2019</td>
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<tr>
<td>Select 22</td>
<td>7</td>
<td>Bob</td>
<td>TestTwo</td>
<td>02/04/2018</td>
</tr>
<tr>
<td>Select 17</td>
<td>9</td>
<td>Catherine</td>
<td>Test-Twentyfive</td>
<td>03/10/2013</td>
</tr>
</tbody>
</table>
Patient Authorized to Receive FINTEPLA

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

Yes  No
Dispense Authorization Number

Patient and Provider Information

<table>
<thead>
<tr>
<th>Patient First Name</th>
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<tbody>
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<td>Patient Echo Due Date</td>
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<td>Last Echo Completion Date Date</td>
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<td>Provider First Name</td>
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<td>Provider Last Name</td>
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<td>Certification Expiration Date</td>
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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
Patient REcosystem Enrollment Complete

Patient NOT Authorized to Receive FINTEPLA.
Patient is Enrolled in REcosystem but does not have a valid Echo, please contact REcosystem Administrator,
877-964-3649

OK
Prescriber Not Certified

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

OK
HCP Not Located

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

New Search  Close
Patient Authorized to Receive FINTEPLA.
Patient has a valid Echo to obtain an Authorization number for the dispense
Patient Not Located

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

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</table>

New Search  Close
**PATIENTS**

How do I receive FINTEPLA?

- 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 their 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.

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.

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.

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

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What do I need to do if I stop taking FINTEPLA?

- If you stop taking FINTEPLA, you will have an ECHO one last time 3 to 6 months after your final dose.

FINTEPLA ECHO Monitoring Timeline

It is important that you read the Medication Guide that comes with your medicine for more information about FINTEPLA. The REMS just covers the risk of heart valve problems and high blood pressure in the arteries of the lungs from the medication. The Medication Guide explains how to take FINTEPLA and has other information about other serious risks and potential side effects.

Where can I find more information about the REMS?

- If you have questions about the REMS, you can visit www.FinteplaREMS.com or call the REMS at 1-877-964-3649 (7 am to 7 pm Central Time).

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

For FINTEPLA REMS Information contact:

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

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