

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

***APPLICATION NUMBER:***

**212102Orig1s000**

**REMS**

# RISK EVALUATION AND MITIGATION STRATEGY (REMS) Document

## FINTEPLA (fenfluramine) REMS Program

### I. Administrative Information

Application Number: NDA 212102  
Application Holder: Zogenix, Inc.  
Initial REMS Approval: 06/2020

### II. REMS Goals

The goal of the FINTEPLA Risk Evaluation and Mitigation Strategy (REMS) Program is to mitigate the risk of valvular heart disease and pulmonary arterial hypertension associated with FINTEPLA, by:

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

### III. REMS Requirements

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

| 1. Healthcare providers who prescribe FINTEPLA must: |                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| To become certified to prescribe                     | <ol style="list-style-type: none"><li>1. Review the drug's Prescribing Information.</li><li>2. Review the following: <a href="#">Prescriber Training</a> and <a href="#">REMS Program Overview</a>.</li><li>3. Successfully complete the <a href="#">Prescriber Knowledge Assessment</a> and submit it to the REMS Program.</li><li>4. Enroll in the REMS by completing the <a href="#">Prescriber Enrollment Form</a> and submitting it to the REMS Program.</li></ol> |

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**1. Healthcare providers who prescribe FINTEPLA must:**

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|------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Before treatment initiation (first dose)       | <ol style="list-style-type: none"><li>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 <a href="#">Patient Guide</a>.</li><li>6. Provide the patient with the <a href="#">Patient Guide</a>.</li><li>7. Enroll the patient by completing and submitting the <a href="#">Patient Enrollment Form</a> to the REMS.</li><li>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 <a href="#">Patient Status Form</a>.</li></ol> |
| During treatment: Every 6 months               | <ol style="list-style-type: none"><li>9. Counsel the patient on the need for cardiac monitoring via echocardiogram every 6 months during treatment using the <a href="#">Patient Guide</a>.</li><li>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 <a href="#">Patient Status Form</a>.</li></ol>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| After treatment discontinuation: 3 to 6 months | <ol style="list-style-type: none"><li>11. Assess the patient's cardiovascular status by obtaining an echocardiogram. Document and submit the results to the REMS Program using the <a href="#">Patient Status Form</a>.</li></ol>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| At all times                                   | <ol style="list-style-type: none"><li>12. Report adverse events suggestive of valvular heart disease and/or pulmonary arterial hypertension on the <a href="#">Cardiovascular Adverse Event Reporting Form</a> to the REMS Program.</li><li>13. Report treatment discontinuation or transfer of care to the REMS Program.</li></ol>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |

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**2. Patients who are prescribed FINTEPLA:**

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|                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Before treatment initiation | <ol style="list-style-type: none"><li>1. Review the <a href="#">Patient Guide</a>.</li><li>2. Enroll in the REMS by completing the <a href="#">Patient Enrollment Form</a> with the prescriber. Enrollment information will be provided to the REMS Program.</li><li>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 <a href="#">Patient Guide</a>.</li><li>4. Get an echocardiogram to check your heart.</li></ol> |
|-----------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

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**2. Patients who are prescribed FINTEPLA:**

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|------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|
| During treatment: Every 6 months               | 5. Receive counseling from the prescriber on the need to get an echocardiogram every 6 months during treatment using the <a href="#">Patient Guide</a> . |
|                                                | 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.                                                                                                 |

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**3. Outpatient pharmacies that dispense FINTEPLA must:**

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|                                       |                                                                                                                                                                                         |
|---------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| To become certified to dispense       | 1. Designate an authorized representative to carry out the certification process and oversee implementation and compliance with the REMS Program on behalf of the pharmacy.             |
|                                       | 2. Have the authorized representative review the <a href="#">Pharmacy Guide</a> and <a href="#">REMS Program Overview</a> .                                                             |
|                                       | 3. Have the authorized representative enroll in the REMS Program by completing the <a href="#">Outpatient Pharmacy Enrollment Form</a> and submitting it to the REMS.                   |
|                                       | 4. Train all relevant staff involved in dispensing FINTEPLA on the REMS requirements using the <a href="#">Pharmacy Guide</a> .                                                         |
| Before dispensing                     | 5. Obtain authorization to dispense by contacting the REMS Program to verify that the prescriber is certified, and the patient is enrolled and authorized to receive the drug.          |
| To maintain certification to dispense | 6. Have the new authorized representative enroll in the REMS Program by completing the <a href="#">Outpatient Pharmacy Enrollment Form</a> 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. |

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**4. Inpatient pharmacies that dispense FINTEPLA must:**

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|                                 |                                                                                                                                                                     |
|---------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| To become certified to dispense | 1. Designate an authorized representative to carry out the certification process and oversee implementation and compliance with the REMS on behalf of the pharmacy. |
|                                 | 2. Have the authorized representative review the <a href="#">Pharmacy Guide</a> and <a href="#">REMS Program Overview</a> .                                         |

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**4. Inpatient pharmacies that dispense FINTEPLA must:**

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

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**5. Wholesale-distributors that distribute FINTEPLA must:**

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

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

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

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

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

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

| Target Audience                                           | Communication Materials and Dissemination Plans                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|-----------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Healthcare providers who are likely to prescribe FINTEPLA | <p>REMS Letter: <a href="#">Letter for Healthcare Providers</a>, with attachments: Prescribing Information, <a href="#">Prescriber Training</a>, and <a href="#">REMS Program Overview</a></p> <ol style="list-style-type: none"> <li>1. Email within 60 calendar days of the date FINTEPLA is first commercially distributed and again 6 months later.               <ol style="list-style-type: none"> <li>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.</li> <li>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.</li> <li>c. Send by mail within 30 calendar days of the date the second email was sent if the second email is marked as unopened.</li> </ol> </li> <li>2. Disseminate through field-based sales representatives and medical science liaisons during initial/follow-up discussion with healthcare providers for 12 months from the date FINTEPLA is first commercially distributed.</li> <li>3. Disseminate through the following professional societies and request the letter or content be provided to their members.               <ol style="list-style-type: none"> <li>a. American Epilepsy Society; Child Neurology Society; American Academy of Neurology.</li> </ol> </li> <li>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.</li> </ol> |

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

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

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

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

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

## IV. REMS Assessment Timetable

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

## V. REMS Materials

The following materials are part of the FINTEPLA REMS:

### Enrollment Forms

Prescriber:

1. [Prescriber Enrollment Form](#)

Patient:

2. [Patient Enrollment Form](#)

Pharmacy:

3. [Outpatient Pharmacy Enrollment Form](#)
4. [Inpatient Pharmacy Enrollment Form](#)

### Training and Educational Materials

Prescriber:

5. [Prescriber Training](#)
6. [REMS Program Overview](#)
7. [Prescriber Knowledge Assessment](#)

Patient:

8. [Patient Guide](#)

Pharmacy:

9. [Pharmacy Guide](#)
10. [REMS Program Overview](#)

### Patient Care Forms

11. [Patient Status Form](#)
12. [Cardiovascular Adverse Event Reporting Form](#)

### Communication Materials

13. [Letter for Healthcare Providers](#)

### Other Materials

14. [REMS Website](#)

## PRESCRIBER INFORMATION

\* indicates required field.

First Name\*:

Practice/Facility Name\*:

## PRESCRIBER AGREEMENT

**PATIENT INFORMATION**

\* indicates required field.

|              |         |       |       |
|--------------|---------|-------|-------|
| First Name*: | Phone*: | Home: | Work: |
|--------------|---------|-------|-------|

**PRESCRIBER INFORMATION**

\* indicates required field.

**PATIENT AGREEMENT****PRESCRIBER AGREEMENT**

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

## STEP 1: REVIEW

## STEP 2: COMPLETE AND SIGN

## STEP 3: SUBMIT

## OUTPATIENT PHARMACY INFORMATION

\* indicates required field.

Pharmacy Name\*:

Pharmacy Address Line 1\*:

## AUTHORIZED REPRESENTATIVE INFORMATION

\* indicates required field.

First Name\*:

Phone\*:

Fax:

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## AUTHORIZED PHARMACY REPRESENTATIVE AGREEMENT

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

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

## STEP 1: REVIEW

## STEP 2: COMPLETE AND SIGN

## STEP 3: SUBMIT

## INPATIENT PHARMACY INFORMATION

\* indicates required field.

Pharmacy Name\*:

Pharmacy Address Line 1\*:

## AUTHORIZED REPRESENTATIVE INFORMATION

First Name\*:

Phone\*:

Fax:

☐☐☐☐☐☐☐

## AUTHORIZED PHARMACY REPRESENTATIVE AGREEMENT

I am the Authorized Representative designated by my Inpatient Pharmacy to coordinate the activities of the REMS.

By completing, signing, and submitting this form, on behalf of myself and my Inpatient Pharmacy, I **attest that**:

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

# Prescriber Training

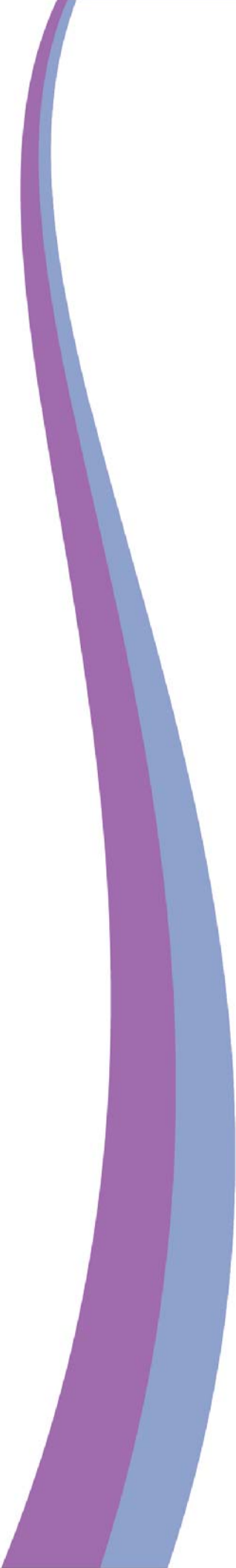
**FINTEPLA® (fenfluramine) oral solution, CIV**  
**Risk Evaluation and Mitigation Strategy (REMS)**

# Welcome to the FINTEPLA REMS Prescriber Training

- To prescribe FINTEPLA, you must become certified in the FINTEPLA REMS, which includes reviewing this training
- After reviewing this training, you must complete and submit a **Prescriber Knowledge Assessment** and a **Prescriber Enrollment Form** before you can prescribe FINTEPLA. You can submit these:
  - **Online** at [www.FinteplaREMS.com](http://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](http://www.FinteplaREMS.com).**

# FINTEPLA Overview



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

# What Is FINTEPLA?

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

# Risk of Valvular Heart Disease and Pulmonary Arterial Hypertension

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

- There is an association between serotonergic drugs with 5-HT<sub>2B</sub> receptor agonist activity, including fenfluramine (the active ingredient in FINTEPLA), and valvular heart disease and pulmonary arterial hypertension
- In clinical trials of FINTEPLA for the treatment of Dravet syndrome, no cases of valvular heart disease or pulmonary hypertension were reported. Across clinical trials of FINTEPLA for the treatment of Dravet syndrome, 0.4-16% of patients taking FINTEPLA were found to have trace aortic or mitral regurgitation compared with 0-6% of patients taking placebo. Trace aortic or mitral regurgitation is considered a physiologic or normal finding in the absence of valvular abnormalities

# FINTEPLA REMS Overview

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

# What Is the FINTEPLA REMS?

- The FINTEPLA REMS (**R**isk **E**valuation and **M**itigation **S**trategy) is a safety program to manage the serious risks of FINTEPLA
  - The FINTEPLA REMS is required by the Food and Drug Administration (FDA) because of the serious risk of valvular heart disease and pulmonary arterial hypertension
- Only prescribers and pharmacies certified by the FINTEPLA REMS can prescribe and dispense FINTEPLA to patients
  - Patients must be enrolled in the FINTEPLA REMS patient registry and follow all the safety rules in the REMS to receive FINTEPLA

# What Do I Need to Do Before Prescribing FINTEPLA?

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

Complete the following 4 steps to become certified:

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

# What Do I Need to Do Prior to Initiating FINTEPLA?

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

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

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

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

Prior to initiating treatment:

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

## How Will My Patient Get FINTEPLA?

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

# Echocardiographic Monitoring During Treatment

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

## Echocardiogram Monitoring Schedule



# Patient Status Form

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

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

**The Patient Status Form must be completed and submitted:**

Before the start of  
FINTEPLA  
treatment

Every 6 months  
with the  
completion of each  
echocardiogram

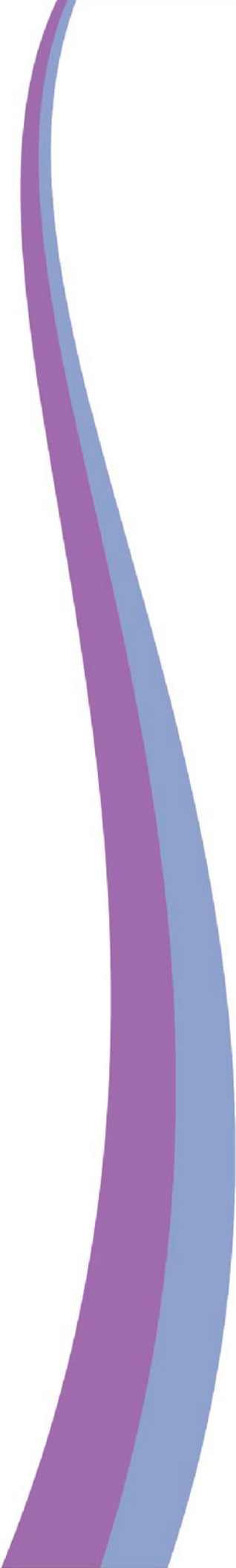
3 to 6 months  
after treatment  
discontinuation with  
the completion of  
the final  
echocardiogram

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

# Cardiovascular Adverse Events Reporting Form

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

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



**This concludes the Prescriber Training.**

# FINTEPLA REMS



## FINTEPLA REMS Program Overview

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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](http://www.FinteplaREMS.com) or call 1-877-964-3649.



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

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

## How Does the FINTEPLA REMS Work?

|                                           | To begin prescribing/<br>dispensing                                      | Before starting FINTEPLA                                                                                                                                                                                                                | During FINTEPLA<br>treatment                                                                                                                                                                                                                                                                                            | After FINTEPLA<br>discontinuation                                                                                                                |
|-------------------------------------------|--------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Prescriber</b>                         | <ul style="list-style-type: none"><li>Prescriber certification</li></ul> | <ul style="list-style-type: none"><li>Counsel the patient</li><li>Enroll the patient</li><li>Assess the patient's CV status via ECHO</li><li>Document and submit the ECHO results and authorization for treatment to the REMS</li></ul> | <ul style="list-style-type: none"><li>Counsel the patient</li><li>Assess the patient's CV status via ECHO</li><li>Document and submit the ECHO results and authorization for treatment to the REMS</li><li>Document and submit ECHO results suggestive of VHD, PAH, or other new CV abnormalities to the REMS</li></ul> | <ul style="list-style-type: none"><li>Assess the patient's CV status via ECHO</li><li>Document and submit the ECHO results to the REMS</li></ul> |
| <b>Pharmacy (outpatient or inpatient)</b> | <ul style="list-style-type: none"><li>Pharmacy certification</li></ul>   |                                                                                                                                                                                                                                         | <ul style="list-style-type: none"><li>Before dispensing, obtain authorization to dispense by contacting the REMS</li></ul>                                                                                                                                                                                              |                                                                                                                                                  |
| <b>Patient</b>                            |                                                                          | <ul style="list-style-type: none"><li>Review the Patient Guide</li><li>Enroll in the REMS with your healthcare provider</li><li>Get an ECHO</li></ul>                                                                                   | <ul style="list-style-type: none"><li>Get an ECHO every 6 months during treatment</li></ul>                                                                                                                                                                                                                             | <ul style="list-style-type: none"><li>Get an ECHO</li></ul>                                                                                      |

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

## What Are the Requirements of the FINTEPLA REMS?

| Prescriber requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Pharmacy requirements                                                                                                                                                                                                                                                                                                                                                                                   | Patient requirements                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"><li><b>Become certified</b><ul style="list-style-type: none"><li>As you start a patient on FINTEPLA, counsel and enroll the patient, evaluate baseline ECHO, and submit ECHO results to the REMS</li></ul></li><li>Perform ongoing monitoring of the patient's CV status via ECHO every 6 months and once 3 to 6 months after treatment discontinuation</li><li>Document and submit the ECHO results and authorization for treatment to the REMS</li><li>Document and submit ECHO results suggestive of PAH, VHD, or other CV abnormalities to the REMS</li><li>Report treatment discontinuation or transfer of care to the REMS</li></ul> | <ul style="list-style-type: none"><li>Designate an authorized representative to certify in the REMS</li><li>Train staff</li><li>Before dispensing, obtain authorization to dispense by contacting the REMS</li><li>Inpatient pharmacies, dispense no more than 15 days' supply at discharge</li><li>Recertify in the REMS if the authorized representative changes</li><li>Comply with audits</li></ul> | <ul style="list-style-type: none"><li>Understand the risks associated with FINTEPLA</li><li>Enroll in the REMS with your healthcare provider</li><li>Get an ECHO to check your heart<ul style="list-style-type: none"><li>Before you start FINTEPLA</li><li>Every 6 months to continue treatment</li><li>Once 3 to 6 months after stopping treatment</li></ul></li><li>Tell your healthcare provider if any signs or symptoms of PAH or VHD develop</li></ul> |

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

## What Are the FINTEPLA REMS Resources?

|                                           | To begin prescribing/<br>dispensing                                                                                                                                                                          | Before starting FINTEPLA                                                                      | During FINTEPLA treatment                                                                                               |
|-------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------|
| <b>Prescriber</b>                         | <ul style="list-style-type: none"><li>Prescribing Information</li><li>REMS Program Overview</li><li>Prescriber Training</li><li>Prescriber Knowledge Assessment</li><li>Prescriber Enrollment Form</li></ul> | <ul style="list-style-type: none"><li>Patient Status Form</li></ul>                           | <ul style="list-style-type: none"><li>Patient Status Form</li><li>Cardiovascular Adverse Event Reporting Form</li></ul> |
| <b>Pharmacy (outpatient or inpatient)</b> | <ul style="list-style-type: none"><li>Pharmacy Guide</li><li>REMS Program Overview</li><li>Outpatient Pharmacy Enrollment Form</li><li>Inpatient Pharmacy Enrollment Form</li></ul>                          |                                                                                               |                                                                                                                         |
| <b>Patient</b>                            |                                                                                                                                                                                                              | <ul style="list-style-type: none"><li>Patient Enrollment Form</li><li>Patient Guide</li></ul> |                                                                                                                         |

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Fintepla®  
(fenfluramine)   
2.2 mg/mL oral solution

ZOGENIX

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• **Fax:** 1-833-568-6198

## PRESCRIBER INFORMATION

\* indicates required field.

First Name\*:

Phone\*:

## PRESCRIBER ASSESSMENT

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

☐☐☐☐☐☐

# FINTEPLA REMS

  
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## Patient/Caregiver Guide



### Patients/Caregivers:

Your healthcare provider will go over this *Patient Guide* with you. It is important that you ask any questions you may have. Keep this guide for important safety information about FINTEPLA.



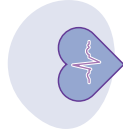
### Healthcare Providers:

Review this *Patient Guide* with your patients and/or their caregivers prior to initiating treatment with FINTEPLA. Give each of them a copy to take home.

## What is FINTEPLA?

FINTEPLA® (fenfluramine) oral solution, CIV, is a medicine used to treat seizures in people with Dravet syndrome who are 2 years of age and older.

## What is the most serious risk of FINTEPLA?



Some adults who took medicines like FINTEPLA developed problems with their heart valves or high blood pressure in the arteries of their lungs. Your healthcare provider will check your heart valves and lung artery pressures with a test called an echocardiogram (ECHO), which is an ultrasound picture of the heart. If your ECHO shows any problems with your heart valves or increased pressures in the lung arteries, your healthcare provider may tell you to stop taking FINTEPLA.

### Tell your healthcare provider right away if you are having any of these signs or symptoms:

- Shortness of breath
- Rapid heartbeat
- Fatigue
- Chest pressure or pain
- Swelling of ankles and feet
- Dizziness or fainting spell

## What is the FINTEPLA REMS?

A **R**isk **E**valuation and **M**itigation **S**trategy (**REMS**) is a drug safety program that the US Food and Drug Administration (FDA) can require for certain medicines with serious safety concerns. Drug companies and healthcare providers must take extra steps to make sure the benefits of using the drug are more than the risks. FDA must approve these steps as part of the REMS.

## Why does FINTEPLA have a REMS?

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



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

- Review this *Patient Guide*
- Talk to your healthcare provider about the information in this *Patient Guide*
- Complete the *Patient Enrollment Form*. Your healthcare provider will help you with this
- Get an ECHO before you start taking FINTEPLA. The ECHO will check for signs of heart valve problems or high blood pressure in the arteries of the lungs
- An ECHO can identify heart valve problems or high blood pressure in the arteries of the lungs before having any symptoms, which may help prevent serious medical problems. Therefore, it is very important to get an ECHO prior to taking FINTEPLA and at regular intervals while on the medicine

## How do I receive FINTEPLA?

- After you and your healthcare provider have discussed your ECHO results and decided to begin or continue FINTEPLA, the REMS will notify the pharmacy of your decision and you will be contacted regarding next steps for obtaining FINTEPLA
- FINTEPLA is available only through pharmacies certified in the REMS. A certified pharmacy will ship the medicine directly to your home

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

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

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

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

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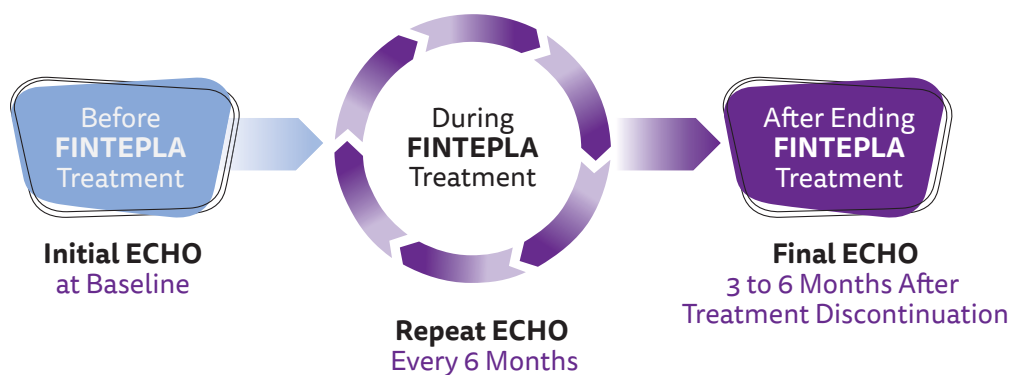
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## FINTEPLA ECHO Monitoring Timeline



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](http://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](http://www.fda.gov/medwatch)).**

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## Pharmacy Guide

---

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



## What Is FINTEPLA?

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

### Risk of valvular heart disease and pulmonary arterial hypertension

Valvular heart disease and pulmonary arterial hypertension have been associated with fenfluramine. There is an association between serotonergic drugs with 5-HT<sub>2B</sub> receptor agonist activity including fenfluramine (the active ingredient in FINTEPLA), and valvular heart disease and pulmonary arterial hypertension. In clinical trials of FINTEPLA for the treatment of Dravet syndrome, no cases of valvular heart disease or pulmonary hypertension were reported. Across clinical trials of FINTEPLA for the treatment of Dravet syndrome, 0.4-1.6% of patients taking FINTEPLA were found to have trace aortic or mitral regurgitation compared with 0-6% of patients taking placebo. Trace aortic or mitral regurgitation is considered a physiologic or normal finding in the absence of valvular abnormalities.

### Monitoring

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

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

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

## What Are the FINTEPLA REMS Requirements?

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

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

|                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|-------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| In order to become certified, the pharmacy must | <ol style="list-style-type: none"><li>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</li><li>2. Have the authorized representative review this <i>Pharmacy Guide</i> and the <i>REMS Program Overview</i></li><li>3. Have the authorized representative enroll in the REMS by completing the <i>Output Patient Pharmacy Enrollment Form</i> or <i>Output Patient Pharmacy Enrollment Form</i>, as appropriate, and submitting it to the REMS</li><li>4. Train all relevant staff involved in dispensing FINTEPLA on the REMS requirements using this <i>Pharmacy Guide</i></li></ol> |
|-------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

## What Are the Responsibilities of Outpatient Pharmacies?

|                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|---------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Before dispensing                     | <ol style="list-style-type: none"><li>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</li></ol>                                                                                                                                                                                                                                                                                                                                                                                         |
| To maintain certification to dispense | <ol style="list-style-type: none"><li>2. Have the new authorized representative enroll in the REMS by completing the <i>Output Patient Pharmacy Enrollment Form</i> if the authorized representative changes</li></ol>                                                                                                                                                                                                                                                                                                                                                                                                             |
| At all times                          | <ol style="list-style-type: none"><li>3. Not distribute, transfer, loan, or sell FINTEPLA, except to certified pharmacies</li><li>4. Maintain records that all processes and procedures are in place and being followed</li><li>5. Maintain records documenting staff's completion of REMS training</li><li>6. Maintain records of dispensing information including patient, prescriber, prescription, and dispensing data</li><li>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</li></ol> |

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## What Are the Responsibilities of Inpatient Pharmacies?

|                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|---------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Before dispensing                     | <ol style="list-style-type: none"> <li>1. For patients initiating treatment: Obtain authorization to dispense FINTEPLA by contacting the REMS to verify that the prescriber is certified, the patient is enrolled, and the patient is authorized to receive the drug</li> <li>2. To continue maintenance therapy: Obtain authorization to dispense FINTEPLA by contacting the REMS to verify that the patient is under the care of a certified prescriber, the patient is enrolled, and the patient is authorized to receive the drug</li> </ol>                                                                                                                                                                                                                                                                          |
| At discharge                          | <ol style="list-style-type: none"> <li>3. Dispense no more than 15 days' supply</li> </ol>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| To maintain certification to dispense | <ol style="list-style-type: none"> <li>4. Have the new authorized representative enroll in the REMS by completing the <i>Inpatient Pharmacy Enrollment Form</i> if the authorized representative changes</li> </ol>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| At all times                          | <ol style="list-style-type: none"> <li>5. Not distribute, transfer, loan, or sell FINTEPLA</li> <li>6. Maintain records that all processes and procedures are in place and being followed</li> <li>7. Maintain records that document staff's completion of REMS training</li> <li>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</li> <li>9. Comply with audits carried out by Zogenix, Inc. or a third party acting on behalf of Zogenix, Inc. to ensure that all processes and procedures are in place and are being followed</li> <li>10. To order FINTEPLA, contact the REMS at 1-877-964-3649</li> </ol> |

### Authorization to Dispense

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

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

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

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

### Additional Risks and Safety Information

The information presented in this guide does not include a complete list of all safety information for FINTEPLA. To review complete safety information on FINTEPLA, please refer to the Prescribing Information for FINTEPLA at [www.FinteplaREMS.com](http://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](http://www.fda.gov/medwatch)).**

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## PATIENT INFORMATION

\* indicates required field.

|              |                  |
|--------------|------------------|
| First Name*: | Address Line 1*: |
|--------------|------------------|

## PRESCRIBER INFORMATION

\* indicates required field.

|              |                  |
|--------------|------------------|
| First Name*: | Address Line 1*: |
|--------------|------------------|

## FINTEPLA DOSING INFORMATION

\* indicates required field.

|                           |           |       |        |
|---------------------------|-----------|-------|--------|
| Current dose of FINTEPLA: | mg/kg/day | Total | mg/day |
|---------------------------|-----------|-------|--------|

## ECHOCARDIOGRAM RESULTS

\* indicates required field.

|                                                 |
|-------------------------------------------------|
| Date of echocardiogram (MM/DD/YYYY)*:    /    / |
|-------------------------------------------------|

Regurgitation (check only 1 box per row)

If echocardiogram report states "mild to moderate" or "moderate to severe," check the more severe category.

| Valve | Absent/Trace             | Mild                     | Moderate                 | Severe                   |
|-------|--------------------------|--------------------------|--------------------------|--------------------------|
|       | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
|       | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
|       |                          |                          |                          | <input type="checkbox"/> |
|       |                          |                          |                          | <input type="checkbox"/> |

## Authorization for Treatment

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

## PATIENT INFORMATION

\* indicates required field.

First Name\*:

Address Line 1\*:

## PRESCRIBER INFORMATION

\* indicates required field.

First Name\*:

Address Line 1\*:

## CARDIOVASCULAR ADVERSE EVENT INFORMATION

\* indicates required field.

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

☐ Valvular heart disease (VHD)☐  
☐  
☐☐☐☐



1710 N Shelby Oaks Drive, Suite 3  
Memphis, TN 38134  
Tel 1-877-964-3649  
Fax 1-833-568-6198

[Month/Day/Year]

## FINTEPLA

### FDA-REQUIRED REMS SAFETY INFORMATION

#### Subject:

- Risk of regurgitant valvular heart disease and/or pulmonary arterial hypertension
- Need for patient echocardiogram (ECHO) monitoring to mitigate the risk

Dear Healthcare Provider:

The purpose of this letter is to inform you about the risk of FINTEPLA and the requirements of the FINTEPLA REMS. The US Food and Drug Administration (FDA) has determined that a Risk Evaluation and Mitigation Strategy (REMS) is necessary to ensure that the benefits of FINTEPLA outweigh its risks.

FINTEPLA is indicated for the treatment of seizures associated with Dravet syndrome in patients 2 years of age and older. Because of the risk of valvular heart disease and pulmonary arterial hypertension associated with FINTEPLA, patients must be monitored with an echocardiogram (ECHO). An echocardiogram can identify evidence of valvular heart disease or pulmonary arterial hypertension prior to a patient becoming symptomatic.

#### Counsel Your Patient

Counsel your patient on the following risks and requirements of the FINTEPLA REMS. Provide your patient with the **Patient Guide** (available at [www.FinteplaREMS.com](http://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](http://www.fda.gov/medwatch)).

For more information regarding the FINTEPLA REMS, please visit [www.FinteplaREMS.com](http://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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## 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](http://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?

- 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](#)
- Successfully complete the Prescriber Knowledge Assessment and submit it to the REMS:
  - [Online](#)
  - [Fax](#)
  - [By Mail](#)
- 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?

- 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.
- Provide the patient with the Patient Guide.
- Enroll the patient by completing and submitting the Patient Enrollment Form to the REMS:
  - [Online](#)
  - [Fax](#)
  - [By Mail](#)
- 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

- Counsel the patient on the need for cardiac monitoring via echocardiogram every 6 months during treatment 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: 3 to 6 months

- 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

- 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.

# 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](http://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*:<br><input type="checkbox"/> Adult Neurology <input type="checkbox"/> Pediatric Neurology<br><input type="checkbox"/> Adult Epileptology <input type="checkbox"/> Pediatric Epileptology<br><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](http://www.FinteplaREMS.com) | Fax: 1-833-568-6198

Fintepla®  
(fenfluramine)   
2.2 mg/mL oral solution



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LOGIN

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## Login

User Name

Password

[Forgot password?](#)

Login

New Prescriber User? [Click here](#) to Create Login  
New Pharmacy User? [Click here](#) to Create Login

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## 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](http://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 FİNTEPLA Prescribing information on 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](http://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 FİNTEPLA 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 FİNTEPLA to a patient, I will:**

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

**During treatment, every 6 months, I will:**

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

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

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

**At all times, I will:**

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

Select Signing Reason

- Select -

☐ Signature \*\*\*

I approve this document

SUBMIT

21CFR 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.fintepla.com](http://www.fintepla.com)  
By fax to 1 833 568 6198  
By mail to 1710 N Shreve 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 *                                                                                                                                |                       |  |
| <input type="text"/>                                                                                                                                                                                                                                                                 | <input type="text"/>                                                                                                                       |                       |  |
| Date of Birth (MM/DD/YYYY) *                                                                                                                                                                                                                                                         | Gender: *<br><input type="radio"/> Male <input type="radio"/> Female <input type="radio"/> Neutral <input type="radio"/> Prefer not to say |                       |  |
| RACE * <input type="radio"/> Black or African American <input type="radio"/> White <input type="radio"/> American Indian or Alaska Native<br><input type="radio"/> Asian <input type="radio"/> Native Hawaiian or Other Pacific Islander <input type="text"/> Other (please specify) |                                                                                                                                            |                       |  |
| ETHNICITY * <input type="radio"/> Hispanic or Latino <input type="radio"/> Not Hispanic or Latino                                                                                                                                                                                    |                                                                                                                                            |                       |  |
| Street Address Line 1 *                                                                                                                                                                                                                                                              |                                                                                                                                            |                       |  |
| <input type="text"/>                                                                                                                                                                                                                                                                 |                                                                                                                                            |                       |  |
| Street Address Line 2                                                                                                                                                                                                                                                                |                                                                                                                                            |                       |  |
| <input type="text"/>                                                                                                                                                                                                                                                                 |                                                                                                                                            |                       |  |
| City *                                                                                                                                                                                                                                                                               | State *                                                                                                                                    | Zip *                 |  |
| <input type="text"/>                                                                                                                                                                                                                                                                 | Select ▼                                                                                                                                   | <input type="text"/>  |  |
| PHONE *                                                                                                                                                                                                                                                                              |                                                                                                                                            |                       |  |
| Home Telephone                                                                                                                                                                                                                                                                       | Work Telephone                                                                                                                             | Cell Phone            |  |
| <input type="text"/>                                                                                                                                                                                                                                                                 | <input type="text"/>                                                                                                                       | <input type="text"/>  |  |
| E-mail *                                                                                                                                                                                                                                                                             |                                                                                                                                            |                       |  |
| <input type="text"/>                                                                                                                                                                                                                                                                 |                                                                                                                                            |                       |  |
| Best Time to Call: <input type="radio"/> AM <input type="radio"/> PM                                                                                                                                                                                                                 |                                                                                                                                            |                       |  |
| Okay to Leave Message: * <input type="radio"/> Yes <input type="radio"/> No                                                                                                                                                                                                          |                                                                                                                                            |                       |  |
| Legal Guardian Name:                                                                                                                                                                                                                                                                 |                                                                                                                                            | Relationship:         |  |
| <input type="text"/>                                                                                                                                                                                                                                                                 |                                                                                                                                            | <input type="text"/>  |  |
| Legal Guardian Phone:                                                                                                                                                                                                                                                                |                                                                                                                                            | Legal Guardian Email: |  |
| <input type="text"/>                                                                                                                                                                                                                                                                 |                                                                                                                                            | <input type="text"/>  |  |

#### Prescriber Information

|                                             |                      |                      |
|---------------------------------------------|----------------------|----------------------|
| National Provider Identifier (NPI) Number * |                      |                      |
| <input type="text"/>                        |                      |                      |
| <div>LOOKUP</div> <div>RESET</div>          |                      |                      |
| First Name *                                | Last Name *          | REMS ID:*            |
| <input type="text"/>                        | <input type="text"/> | <input type="text"/> |
| Prescriber Email                            | Prescriber Phone *   | Prescriber Fax *     |
| <input type="text"/>                        | <input type="text"/> | <input type="text"/> |
| Address Line 1 *                            |                      |                      |
| <input type="text"/>                        |                      |                      |
| Address Line 2                              |                      |                      |
| <input type="text"/>                        |                      |                      |
| City *                                      | State *              | ZIP Code *           |
| <input type="text"/>                        | Select ▼             | <input type="text"/> |

#### 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 FİNTEPLA, 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 FİNTEPLA.

**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 lightheadedness
- 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 FİNTEPLA, and releasing my personal health information to the Food and Drug Administration (FDA), as necessary.
- In order to receive FİNTEPLA, I am required to be enrolled in the REMS, and my information will be stored in a database of all participants who receive FİNTEPLA in the United States.

|                                                                                                                             |          |
|-----------------------------------------------------------------------------------------------------------------------------|----------|
| Select Signing Reason                                                                                                       | Select ▼ |
| <input type="checkbox"/> Parent or Legal Guardian Signature *<br><input type="checkbox"/> Patient Signature (if applicable) |          |
| <div>SUBMIT</div>                                                                                                           |          |

|                                                                                                                                         |          |
|-----------------------------------------------------------------------------------------------------------------------------------------|----------|
| <b>Prescriber Agreement</b>                                                                                                             |          |
| By signing below, I acknowledge that I have reviewed the risks of FİNTEPLA and the requirements of the FİNTEPLA REMS with this patient. |          |
| Select Signing Reason                                                                                                                   | Select ▼ |
| <input type="checkbox"/> Prescriber Signature *                                                                                         |          |
| <div>SUBMIT</div>                                                                                                                       |          |



## 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 FİNTEPLA 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 FİNTEPLA:

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

Submit the completed form online at [www.FinteplaREMS.com](http://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](http://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              |
| <input type="text"/>         | <input type="text"/> | <input type="text"/> |
| Date of Birth (MM/DD/YYYY) * |                      |                      |
| <input type="text"/>         |                      |                      |
| Street Address - line 1 *    |                      |                      |
| <input type="text"/>         |                      |                      |
| Street Address - line 2      |                      |                      |
| <input type="text"/>         |                      |                      |
| City *                       | State *<br>Select ▼  | Zip *                |
| <input type="text"/>         | <input type="text"/> | <input type="text"/> |
| Height:                      | Weight:              | BMI                  |
| <input type="text"/>         | <input type="text"/> | <input type="text"/> |

### Prescriber Information

|                                      |                      |                      |
|--------------------------------------|----------------------|----------------------|
| First Name *                         | Last Name *          | REMS ID              |
| <input type="text"/>                 | <input type="text"/> | <input type="text"/> |
| National Provider Identifier (NPI) * |                      |                      |
| <input type="text"/>                 |                      |                      |
| Street Address - line 1 *            |                      |                      |
| <input type="text"/>                 |                      |                      |
| Street Address - line 2              |                      |                      |
| <input type="text"/>                 |                      |                      |
| City *                               | State *<br>Select ▼  | Zip *                |
| <input type="text"/>                 | <input type="text"/> | <input type="text"/> |
| Telephone Number *                   | Fax Number *         | E-mail               |
| <input type="text"/>                 | <input type="text"/> | <input type="text"/> |

### FİNTEPLA Dosing Information

|                           |                      |                                              |
|---------------------------|----------------------|----------------------------------------------|
| Current Dose of FİNTEPLA: |                      |                                              |
| mg/kg/day                 | Total mg/day         | Current Duration of treatment with FİNTEPLA: |
| <input type="text"/>      | <input type="text"/> | <input type="text"/>                         |

### 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) *                                         |                       | <input type="radio"/> Yes | <input type="radio"/> No |                       |
| Any valvular abnormality reported on on baseline echocardiogram (only applicable to baseline echocardiogram assessment) |                       | <input type="radio"/> Yes | <input type="radio"/> No |                       |
| Any new abnormality on echocardiogram (not previously reported)                                                         |                       | <input type="radio"/> Yes | <input type="radio"/> No |                       |

| Authorization for Treatment                                                                                    |                                                                      |
|----------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------|
| Is this patient authorized to receive FİNTEPLA? (select one) *                                                 |                                                                      |
| <input type="radio"/> Yes <input type="radio"/> No                                                             |                                                                      |
| If this patient is not authorized to receive FİNTEPLA, please provide the reason(s): (select all that apply) * |                                                                      |
| <input type="checkbox"/> Changes in the echocardiogram or abnormal echocardiogram                              | <input type="checkbox"/> New diagnosis of VHD or PAH                 |
| <input type="checkbox"/> Noncompliance with echocardiogram                                                     | <input type="checkbox"/> Other (please specify) <input type="text"/> |

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 FİNTEPLA REMS within 3 business days of receipt.

|                                      |                                                                            |
|--------------------------------------|----------------------------------------------------------------------------|
| Submitted by: *                      | <input type="radio"/> Prescriber Designee <input type="radio"/> Prescriber |
| Select Signing Reason                | Select ▼                                                                   |
| <input type="checkbox"/> 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](http://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](http://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 *            |
| <input type="text"/>         | <input type="text"/>                | <input type="text"/> |
| Date of Birth (MM/DD/YYYY) * |                                     |                      |
| <input type="text"/>         |                                     |                      |
| Street Address line 1 *      |                                     |                      |
| <input type="text"/>         |                                     |                      |
| Street Address line 2        |                                     |                      |
| <input type="text"/>         |                                     |                      |
| City *                       | State *                             | Zip *                |
| <input type="text"/>         | <input type="text" value="Select"/> | <input type="text"/> |

#### Prescriber Information

|                                      |                                     |                      |
|--------------------------------------|-------------------------------------|----------------------|
| First Name *                         | Last Name *                         | REMS ID *            |
| <input type="text"/>                 | <input type="text"/>                | <input type="text"/> |
| National Provider Identifier (NPI) * |                                     |                      |
| <input type="text"/>                 |                                     |                      |
| Street Address line 1 *              |                                     |                      |
| <input type="text"/>                 |                                     |                      |
| Street Address line 2                |                                     |                      |
| <input type="text"/>                 |                                     |                      |
| City *                               | State *                             | Zip *                |
| <input type="text"/>                 | <input type="text" value="Select"/> | <input type="text"/> |
| Telephone Number *                   | Fax Number *                        | E-mail               |
| <input type="text"/>                 | <input type="text"/>                | <input type="text"/> |

#### Cardiovascular Adverse Event Information

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

|                                                                                                                                                                     |                                                                                                            |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------|
| <input type="checkbox"/> Valvular heart disease (VHD)                                                                                                               | <input type="checkbox"/> Moderate or greater mitral regurgitation (State degree of mitral regurgitation: ) |
| <input type="checkbox"/> Mild or greater aortic regurgitation (State degree of aortic regurgitation: )                                                              | <input type="checkbox"/> Valve thickening (aortic and mitral valves) (Which valve(s)? )                    |
| <input type="checkbox"/> Restricted valve motion (aortic and mitral valves) (Which valve(s)? )                                                                      | <input type="checkbox"/> Valve thickening (aortic and mitral valves) (Which valve(s)? )                    |
| <input type="checkbox"/> Pulmonary Arterial Hypertension (PAH)                                                                                                      |                                                                                                            |
| Echocardiogram findings of PAH (select all that apply):                                                                                                             |                                                                                                            |
| <input type="checkbox"/> Interventricular septal flattening                                                                                                         |                                                                                                            |
| <input type="checkbox"/> Elevated right heart/pulmonary artery pressure (pulmonary artery systolic pressure >35 mm Hg) (PASP reading was <input type="text"/> mmHg) |                                                                                                            |
| <input type="checkbox"/> Other (please specify): <input type="text"/>                                                                                               |                                                                                                            |
| <input type="checkbox"/> Other cardiac valve abnormalities (select all that apply):                                                                                 |                                                                                                            |
| <input type="checkbox"/> Mild or greater pulmonic valve regurgitation (State degree of regurgitation: ) <input type="text"/>                                        |                                                                                                            |
| <input type="checkbox"/> Moderate or greater tricuspid valve regurgitation (State degree of regurgitation: ) <input type="text"/>                                   |                                                                                                            |
| <input type="checkbox"/> Other (please specify): <input type="text"/>                                                                                               |                                                                                                            |
| Dose of FINTEPLA at the time of the event: * <input type="text"/> mg/kg/day * and <input type="text"/> mg/day *                                                     |                                                                                                            |
| Is patient on concomitant Sildenafil? * <input type="radio"/> Yes <input type="radio"/> No                                                                          |                                                                                                            |
| Duration of treatment with FINTEPLA (provide treatment dates): * <input type="text"/>                                                                               |                                                                                                            |
| Was treatment discontinued due to this event? * <input type="radio"/> Yes <input type="radio"/> No                                                                  |                                                                                                            |
| Was the patient symptomatic? * <input type="radio"/> Yes <input type="radio"/> No                                                                                   |                                                                                                            |
| If yes, please describe symptoms: <input type="text"/>                                                                                                              |                                                                                                            |
| Were there any signs on physical exam? * <input type="radio"/> Yes <input type="radio"/> No                                                                         |                                                                                                            |
| If yes, please describe signs: <input type="text"/>                                                                                                                 |                                                                                                            |
| <input type="checkbox"/> Did the VHD, PAH, or other cardiac valve abnormality result in any of the following (check all that apply):                                |                                                                                                            |
| <input type="checkbox"/> Medication or interventional therapy <input type="checkbox"/> Discontinuation of treatment                                                 |                                                                                                            |
| <input type="checkbox"/> Hospitalization <input type="checkbox"/> No change                                                                                         |                                                                                                            |
| <input type="checkbox"/> 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



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LOGIN

PRESCRIBERS

PHARMACIES

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## 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 \*

☐

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## PHARMACIES

### Outpatient Pharmacy Requirements

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

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

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

##### Before dispensing FINTEPLA

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

##### To maintain certification to dispense

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

##### At all times

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

### Inpatient Pharmacy Requirements:

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

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

#### To Ensure Compliance with the REMS Requirements Pharmacies must:

##### Before dispensing FINTEPLA

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

##### At discharge

1. Dispense no more than 15 days' supply.

##### To maintain certification to dispense

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

##### At all times

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



## OUTPATIENT PHARMACY

### Outpatient Pharmacy Enrollment Form

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

#### STEP 1: REVIEW

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

#### STEP 2: COMPLETE AND SIGN

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

#### STEP 3: SUBMIT

- Submit the form via
  - Online at [www.FinteplaREMS.com](http://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                                                                                                                                           |
| <input type="text"/>               | <input type="text"/>                                                                                                                                 |
| E-mail *                           |                                                                                                                                                      |
| <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                 | - Select - ▼ |
| <input type="checkbox"/> Signature *  |              |
| <input type="button" value="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](http://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

### Tools

Verify Prescriber Certification  
& Patient Enrollment

VERIFY

Obtain Dispense  
Authorization Number

START

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## Prescriber



First Name

Last Name

National Provider Identifier (NPI)

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### Prescriber List

|                        | HCP ID | First Name ▲ | Last Name  | State License No | State of License | NPI        |
|------------------------|--------|--------------|------------|------------------|------------------|------------|
| <a href="#">Select</a> | 19     | ADAM         | NUMIS      | A116439          | CA               | 1093943508 |
| <a href="#">Select</a> | 18     | AIMEE        | LUAT       | 4301082592       | MI               | 1326216821 |
| <a href="#">Select</a> | 50     | ALAN         | FREEMAN    | 26271            | GA               | 1124132766 |
| <a href="#">Select</a> | 29     | ANDREW       | SHEILS     | 13081            | GA               | 1982677951 |
| <a href="#">Select</a> | 15     | ASIM         | SHAHID     | 35.094552        | OH               | 1962616730 |
| <a href="#">Select</a> | 16     | DAVID        | BURKHOLDER | 52949            | MIN              | 1598956722 |
| <a href="#">Select</a> | 26     | Dialecti     | Voudouris  |                  |                  | 1174575187 |
| <a href="#">Select</a> | 27     | DINESH       | TALWAR     | 20354            | AZ               | 1831168566 |
| <a href="#">Select</a> | 1      | DOLICI AS    | SMITH      | RD589            | MIN              | 1518265725 |

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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   or  
Patient Authorized-Warning

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Reference ID: 631870

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## Patient List

Patient First Name

MRN

Search

Reset

### Patient REMS Enrollment Complete

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

OK

No baseline Patient Status Form  
or outside 270 days of Date of  
Last Status Form

## Patients

| Hubid     | MRN | Patient First Name ▲ | Patient Last Name | Patient DOB      |
|-----------|-----|----------------------|-------------------|------------------|
| Select 22 | Bob | TestTwo              | 02/04/2018        | 1 • 1 of 1 items |

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## Prescriber

First Name

Identifier (NPI)

Search

Reset

HCP List

HubId

MRN

Select 22

1

Patient DOB

02/04/2018

1 of 1 items



### 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 List

|                        | HCP ID | First Name            | State of License | NPI        |
|------------------------|--------|-----------------------|------------------|------------|
| <a href="#">Select</a> | 19     | ADAM                  | MI               | 1093943508 |
| <a href="#">Select</a> | 18     | AIMEE                 | GA               | 1326216821 |
| <a href="#">Select</a> | 50     | ALAN                  | GA               | 1124132766 |
| <a href="#">Select</a> | 29     | ANDREW                | GA               | 1982677951 |
| <a href="#">Select</a> | 15     | ASIM                  | OH               | 1962616730 |
| <a href="#">Select</a> | 16     | DAVID                 | MIN              | 1596995722 |
| <a href="#">Select</a> | 28     | Dialecti<br>Voudouris |                  | 1174575187 |
| <a href="#">Select</a> | 27     | DINESH                | AZ               | 1831168568 |
| <a href="#">Select</a> | 1      | DOLIGLAS<br>SMITH     | MIN              | 1518285725 |

### 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

Hello, UserName@email.com

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## Patient List



Patient First Name

MRN

Search

Reset

### Patient REMS Enrolled Valid Echo



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

OK

 Patients

|        | Hubid | MRN | Patient First Name * | Patient Last Name | Patient DOB  |
|--------|-------|-----|----------------------|-------------------|--------------|
| Select | 22    |     | Bob                  | TestTwo           | 02/04/2018   |
| 1      |       |     |                      |                   | 1 of 1 items |

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## 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 |
|------------------------|-------|-----|----------------------|-------------------|-------------|
| <a href="#">Select</a> | 19    |     | Alice                | Test-One          | 01/02/2018  |
| <a href="#">Select</a> | 14    |     | Amy                  | Test-Nineteen     | 02/02/2017  |
| <a href="#">Select</a> | 18    |     | Ann                  | Gatestone         | 02/15/2019  |
| <a href="#">Select</a> | 22    |     | Bob                  | TestTwo           | 02/04/2018  |
| <a href="#">Select</a> | 17    |     | Catherine            | Test-Twentyfive   | 03/10/2013  |



## PATIENTS

### What is FINTEPLA?

FINTEPLA is a medicine used to treat seizures in people with Dravet syndrome who are 2 years of age and older.

### What is the most serious risk of FINTEPLA?

Some adults who took medicines like FINTEPLA developed problems with their heart valves or high blood pressure in the arteries of their lungs. Your healthcare provider will check your heart valves and lung artery pressures with a test called an echocardiogram (ECHO), which is an ultrasound picture of the heart. If your ECHO shows any problems with your heart valves or increased pressures in the lung arteries, your healthcare provider may tell you to stop taking FINTEPLA.

Tell your healthcare provider right away if you are having any of these signs or symptoms:

- Shortness of breath
- Rapid heartbeat
- Fatigue
- Chest pressure or pain
- Swelling of ankles and feet
- Dizziness or fainting spell

### What is the FINTEPLA REMS?

A 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](http://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](http://www.fda.gov/medwatch)).



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## CONTACT US

For FINTEPLA REMS Information contact:

FINTEPLA REMS

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Memphis, TN 38134

Phone: 877-964-3649

Fax: 833-568-6198

[www.FinteplaREMS.com](http://www.FinteplaREMS.com)

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/s/  
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