

# 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/ dispensing	Before starting FINTEPLA	During FINTEPLA treatment	After FINTEPLA discontinuation
<b>Prescriber</b>	<ul style="list-style-type: none"> <li>Prescriber certification</li> </ul>	<ul style="list-style-type: none"> <li><b>Counsel</b> the patient</li> <li><b>Enroll</b> the patient</li> <li><b>Assess</b> the patient's CV status via ECHO</li> <li><b>Document and submit</b> the ECHO results and authorization for treatment to the REMS</li> </ul>	<ul style="list-style-type: none"> <li><b>Counsel</b> the patient</li> <li><b>Assess</b> the patient's CV status via ECHO</li> <li><b>Document and submit</b> the ECHO results and authorization for treatment to the REMS</li> <li><b>Document and submit</b> ECHO results suggestive of VHD, PAH, or other new CV abnormalities to the REMS</li> </ul>	<ul style="list-style-type: none"> <li><b>Assess</b> the patient's CV status via ECHO</li> <li><b>Document and submit</b> 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, <b>obtain authorization to dispense</b> by contacting the REMS</li> </ul>	
<b>Patient</b>		<ul style="list-style-type: none"> <li><b>Review</b> the <i>Patient Guide</i></li> <li><b>Enroll</b> in the REMS with your healthcare provider</li> <li><b>Get an ECHO</b></li> </ul>	<ul style="list-style-type: none"> <li><b>Get an ECHO every 6 months during treatment</b></li> </ul>	<ul style="list-style-type: none"> <li><b>Get an ECHO</b></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></li> <li>As you start a patient on FINTEPLA, <b>counsel and enroll</b> the patient, evaluate baseline ECHO, and submit ECHO results to the REMS</li> <li>Perform ongoing <b>monitoring of the patient's CV status via ECHO</b> every 6 months and once 3 to 6 months after treatment discontinuation</li> <li><b>Document and submit</b> the ECHO results and authorization for treatment to the REMS</li> <li><b>Document and submit</b> ECHO results suggestive of PAH, VHD, or other CV abnormalities to the REMS</li> <li><b>Report</b> treatment discontinuation or transfer of care to the REMS</li> </ul>	<ul style="list-style-type: none"> <li><b>Designate</b> an authorized representative to certify in the REMS</li> <li><b>Train</b> staff</li> <li>Before dispensing, <b>obtain authorization to dispense</b> by contacting the REMS</li> <li>Inpatient pharmacies, <b>dispense</b> no more than 15 days' supply at discharge</li> <li><b>Recertify</b> in the REMS if the authorized representative changes</li> <li><b>Comply</b> with audits</li> </ul>	<ul style="list-style-type: none"> <li><b>Understand</b> the risks associated with FINTEPLA</li> <li><b>Enroll</b> in the REMS with your healthcare provider</li> <li><b>Get an ECHO to check your heart</b> <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><b>Tell</b> 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/ 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><i>Patient Status Form</i></li> </ul>	<ul style="list-style-type: none"> <li><i>Patient Status Form</i></li> <li><i>Cardiovascular Adverse Event Reporting Form</i></li> </ul>
<b>Pharmacy (outpatient or inpatient)</b>	<ul style="list-style-type: none"> <li><i>Pharmacy Guide</i></li> <li>REMS Program Overview</li> <li><i>Outpatient Pharmacy Enrollment Form</i></li> <li><i>Inpatient Pharmacy Enrollment Form</i></li> </ul>		
<b>Patient</b>		<ul style="list-style-type: none"> <li><i>Patient Enrollment Form</i></li> <li><i>Patient Guide</i></li> </ul>	

  
Fintepla®  
(fenfluramine)  
2.2 mg/mL oral solution



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