

FINTEPLA REMS Cardiovascular Adverse Event Reporting Form

FOR PRESCRIBERS

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

Instructions

Within 3 business days of receipt, complete this form and submit the completed form online at www.FinteplaREMS.com, via fax to 1-833-568-6198, or via mail to 1710 N Shelby Oaks Dr, Ste 3, Memphis, TN 38134.

PATIENT INFORMATION				
First Name*:	Address Line 1*:			
Last Name*:	Address Line 2:			
Date of Birth (MM/DD/YYYY)*: / /	REMS ID*:	City*:	State*:	ZIP Code*:

PRESCRIBER INFORMATION				
First Name*:	Address Line 1*:			
Last Name*:	Address Line 2:			
National Provider Identifier (NPI)*:	City*:	State*:	ZIP Code*:	
REMS ID*:	Phone*:	-	-	
Email:	Fax*:	-	-	

CARDIOVASCULAR ADVERSE EVENT INFORMATION				
Cardiac findings on echocardiogram (select all that apply)*:				
<input type="checkbox"/> Valvular heart disease (VHD)				
<input type="checkbox"/> Mild or greater aortic regurgitation (State degree of aortic regurgitation: _____)	<input type="checkbox"/> Moderate or greater mitral regurgitation (State degree of mitral regurgitation: _____)	<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 _____ mm Hg		<input type="checkbox"/> Other (please specify): _____	
<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="checkbox"/> Moderate or greater tricuspid valve regurgitation (State degree of regurgitation: _____)				
<input type="checkbox"/> Other (please specify): _____				
Dose of FINTEPLA at the time of the event*:		_____ mg/kg/day	and	_____ mg/day
Is patient on concomitant stiripentol?* <input type="checkbox"/> Yes <input type="checkbox"/> No				
Duration of treatment with FINTEPLA (provide treatment dates)*: _____				
Was treatment discontinued due to this event?* <input type="checkbox"/> Yes <input type="checkbox"/> No				
Was the patient symptomatic?* <input type="checkbox"/> Yes <input type="checkbox"/> No				
If yes, please describe symptoms*:				
Were there any signs on physical exam?* <input type="checkbox"/> Yes <input type="checkbox"/> No				
If yes, please describe signs*:				
Did the VHD, PAH, or other cardiac valve abnormalities result in any of the following (check all that apply):				
<input type="checkbox"/> Medication or interventional therapy	<input type="checkbox"/> Hospitalization	<input type="checkbox"/> Discontinuation of treatment	<input type="checkbox"/> Death	<input type="checkbox"/> No change
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.				
_____ Signature		_____ Print Name		_____ Date
Submitted by: <input type="checkbox"/> Prescriber Designee <input type="checkbox"/> Prescriber				
If the patient has been discontinued from FINTEPLA treatment, the prescriber/prescriber designee must notify the FINTEPLA REMS.				

If you have any questions or need additional information, please visit www.FinteplaREMS.com or call 1-877-964-3649, Monday through Friday, between 7 AM and 7 PM Central Time.



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

