

PHP Procedure Outcome Form

HEPZATO KIT™
(melphalan) for Injection/
Hepatic Delivery System (HDS)

PHONE: 1-833-632-0457
EMAIL: coordinator@HEPZATOKITREMS.com
WEB: www.HEPZATOKITREMS.com

INSTRUCTIONS

HEPZATO KIT is only available through the HEPZATO KIT Risk Evaluation and Mitigation Strategy (REMS) to mitigate the risks of severe peri-procedural complications including hemorrhage, hepatocellular injury, and thromboembolic events.

Healthcare settings that dispense HEPZATO KIT must be certified and percutaneous hepatic perfusion (PHP) procedure team members who perform PHP procedures with HEPZATO KIT must be qualified. Log the outcome of each PHP procedure by completing and submitting this form to the REMS Coordinating Center via email at coordinator@HEPZATOKITREMS.com or online at www.HEPZATOKITREMS.com.

Authorized Representative (all fields are required)			
First Name:	Last Name:		
Email:	Phone:		
Department:			
Healthcare Setting Information (all fields are required)			
Healthcare Setting Name:			
Address Line 1:			
Address Line 2:			
City:	State:	Zip Code:	
Percutaneous Hepatic Perfusion Procedure Date			
Procedure Date:			
Patient Initials:	Patient DOB:	Patient Gender: Male Female Other Prefer not to answer	
HEPZATO KIT Used (Lot #):			
Percutaneous Hepatic Perfusion Procedure Outcome			
Outcome	Yes	No	
Completed: The PHP procedure was completed and the patient received infusion of HEPZATO (melphalan).			
Not Completed: The PHP procedure was attempted but was aborted (please provide details below).			
Cancelled: The planned PHP procedure was cancelled and was not attempted. Note: if rescheduling a PHP procedure, you must complete a new Procedure Team Qualification Status Form and submit to the REMS in order to receive a new Authorization to Dispense.			

If the procedure was Not Completed, please provide details:

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Device Components		
Were any device or accessory substitutions made during the procedure?	Yes	No
If Yes, please specify which components were used and the HEPZATO KIT the components were taken from:		

During and after administering HEPZATO KIT, for at least 72 hours, the healthcare setting must assess the patient for severe peri-procedural complications associated with HEPZATO KIT. Severe peri-procedural complications including hemorrhage, hepatocellular injury, and thromboembolic events must be submitted by completing the Severe Peri-Procedure-Related Complications Adverse Events Documentation Form to the REMS Coordinating Center.