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

Severe Peri-Procedure-Related Complications Adverse Events Documentation Form

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 risk of severe peri-procedural complications including hemorrhage, hepatocellular injury, and thromboembolic events associated with HEPZATO KIT.

During and for at least 72 hours after administering HEPZATO KIT, patients must be assessed for severe peri-procedural complications following the percutaneous hepatic perfusion (PHP) procedure. Follow up may occur virtually or via telephone for patients discharged prior to 72 hours.

Severe peri-procedural complications including hemorrhage, hepatocellular injury, and thromboembolic events must be reported by completing and submitting this form to the REMS Coordinating Center via e-mail at coordinator@HEPZATOKITREMS.com or online at www.HEPZATOKITREMS.com.

Any severe peri-procedural complications including hemorrhage, hepatocellular injury, and thromboembolic events that may be identified within 72 hours of administration of HEPZATO KIT, are required to be reported within 24 hours of awareness to Delcath Systems, Inc. at 1-833-632-0457 or www.Delcath.com or to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Reporter Information (all fields are required)	
First Name:	Last Name:
Email:	Phone:
Credentials: ☐ MD ☐ DO ☐ RN ☐ PharmD/RPh ☐ NP/PA ☐ Other (please specify)	
Title:	

Healthcare Setting Information (all fields are required)		
Healthcare Setting Name:	REMS ID:	
Address Line 1:		
Address Line 2:		
City:	State:	Zip Code:

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SERIOUS ADVERSE EVENT REPORTING

Complete the below to report severe peri-procedural complications including hemorrhage, hepatocellular injury, and thromboembolic events.

Date of the PHP Procedure: (MM/DD/YYYY)		**Date of Onset of the Serious Adverse Event: (MM/DD/YYYY)**
Patient Initials:	**Date of Birth: (MM/DD/YYYY)**	**Gender:** ☐ Male ☐ Female ☐ Other ☐ Prefer Not to Answer

	If Yes, Seriousness Criteria for Each Event				
Event	**Death**	**Hospitalization**	**Life-Threatening**	**Important Medical Event**	**The PHP procedure was aborted due to this event**
Hemorrhage ☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Hepatocellular injury ☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Thromboembolic events ☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Other Severe Peri-procedural Complications	**Death**	**Hospitalization**	**Life-Threatening**	**Important Medical Event**	**The PHP procedure was aborted due to this event**
	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No

Please provide any additional Details of Event(s), including any signs and symptoms of hemorrhage, any liver enzyme elevations (ALT/AST) above 3x ULN or any signs of symptoms of liver injury, any signs and symptoms of thromboembolic event, or other serious adverse events attributable to the procedure. Include details, rationale, and root cause related to the percutaneous hepatic perfusion procedure that further describe the adverse event. If PHP procedure was aborted, describe the reasons in detail.

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By signing this form, you consent to having the percutaneous hepatic perfusion procedure team contacted for further information regarding this report of a serious adverse event. Pertinent laboratory results will be requested.

REPORTER INFORMATION (all fields are required)	
First Name:	Last Name:
Phone:	Email:
Reporter Signature:	**Date (MM/DD/YYYY):**

Definitions of seriousness criteria:

- Fatal - Report adverse events that occurred during or shortly after the procedure and that you suspect resulted in or lead to death (i.e., the AE causes or leads to death).
- Life-threatening – Report adverse events that in your opinion put the patient at substantial risk of dying, or use or continued use of product might have resulted in the death of the patient. This does not include any AE that, had it occurred in a more serious form or was allowed to continue, might have caused death.
- Requires or prolongs inpatient hospitalization. Report if admission to the hospital or prolongation of hospitalization was a result of an adverse event that occurred during of shortly after the procedure. Emergency room visits that do not result in admission to the hospital should be evaluated for one of the other serious outcomes (e.g., life-threatening; required intervention to prevent permanent impairment or damage; other serious medically important event).
- Adverse Event which results in persistent or significant disability/incapacity (i.e., the AE results in substantial disruption of the patient's ability to conduct normal life functions).
- Adverse Event which results in congenital anomaly/birth defect in a neonate/infant born to a mother exposed to study drug.
- Any other significant Medical Events that in the treating physician's judgment may jeopardize the patient or may require medical/surgical intervention to prevent one of the outcomes listed above.

Note: The terms "severe" and "serious" are not synonymous. Severity refers to the intensity of an AE (rated as mild, moderate, or severe, or according to the NCI CTCAE criteria).

The event itself may be of relatively minor medical significance (such as severe headache without any further findings). Severity and seriousness must be independently assessed for each AE.

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