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

HEPZATO KIT REMS Program

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

What is the HEPZATO KIT REMS?

The HEPZATO KIT REMS (Risk Evaluation and Mitigation Strategy) is required by the US Food and Drug Administration (FDA) to ensure that the benefits of HEPZATO KIT outweigh the risks.

The goal of the HEPZATO KIT REMS is to mitigate the risks of severe peri-procedural complications including hemorrhage, hepatocellular injury, and thromboembolic events associated with HEPZATO KIT.

Severe Peri-Procedural Complications

- Hemorrhage, hepatocellular injury, and thromboembolic events have been observed when HEPZATO has been administered via hepatic intra-arterial administration.
- Administration of HEPZATO requires general anesthesia and extracorporeal bypass of circulation which may cause life threatening or fatal adverse effects.
- Ensure the patient is euvolemic but do not overhydrate the patient.
- Monitor for these peri-procedural complications during the procedure and for at least 72 hours following the procedure.

What is the HEPZATO KIT?

HEPZATO KIT (HEPZATO for Injection/Hepatic Delivery System) is a closed circuit of catheters and filters utilized to deliver HEPZATO (melphalan) to the hepatic artery and to lower the concentration of the agent in the blood before it is returned to systemic circulation.

HEPZATO KIT (HEPZATO for Injection/Hepatic Delivery System) is indicated as a liver-directed treatment for adult patients with uveal melanoma with unresectable hepatic metastases affecting less than 50% of the liver and no extrahepatic disease, or extrahepatic disease limited to the bone, lymph nodes, subcutaneous tissues, or lung that is amenable to resection or radiation.

What are the HEPZATO KIT REMS requirements?

- Only certified healthcare settings can dispense HEPZATO KIT
- Certified healthcare settings must:
  - Have a percutaneous hepatic perfusion procedure team(s) that must include healthcare providers with expertise in interventional radiology, anesthesiology, and perfusion as described in the Instructions for Use.
  - Have the following on-site: interventional radiology suite or operating room with fluoroscopy and with resuscitation personnel, equipment, and medications.
  - Designate an Authorized Representative (AR) to carry out the certification process and oversee implementation and compliance with the REMS requirements on behalf of the healthcare setting.
- The percutaneous hepatic perfusion procedure team members must complete training to participate in procedures with HEPZATO KIT.
- During and after administering, for at least 72 hours, the healthcare setting must assess the patient for severe peri-procedural complications associated with HEPZATO KIT, document severe peri-procedural complications using the **Severe Peri-Procedure-related Complications Adverse Events Documentation Form** and submit to the REMS.

How does a healthcare setting become certified in the HEPZATO KIT REMS?

The healthcare setting must designate an AR to carry out the certification process and oversee implementation and compliance with the REMS requirements on behalf of the Healthcare Setting.

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The AR must:

- Review the product's Prescribing Information, Instructions for Use, **Program Overview**, and **Didactic Modules.**
- Enroll in the REMS Program by completing and submitting the **Healthcare Setting Enrollment Form** to the REMS.
- Have the percutaneous hepatic perfusion team member that performs procedures with HEPZATO KIT review the product's Prescribing Information and Instructions for Use.
- Have the percutaneous hepatic perfusion team members that performs procedures with HEPZATO KIT review the **Program Overview**, **Didactic Modules**, and undergo the Preceptorship training provided by Delcath Systems, Inc.
- Have the percutaneous hepatic perfusion team members that performs procedures with HEPZATO KIT successfully complete the Proctorship training and complete and submit the **Criteria for Procedural Competency Checklist** to the REMS.
    - Delcath Systems, Inc. will coordinate with the AR to schedule the Preceptorship training and Proctorship training.
- Establish processes and procedures to ensure relevant staff who are new to the team and will perform percutaneous hepatic perfusion procedures with HEPZATO KIT are trained
    - Completed checklists should be maintained in training records at the healthcare setting.
- At all times:
    - Maintain records of each percutaneous hepatic perfusion procedure team member's training.
    - Maintain records of the percutaneous hepatic perfusion procedures performed with HEPZATO KIT and the associated percutaneous hepatic perfusion procedure team members' participation.
    - Maintain records that processes and procedures are in place and are being followed.
    - Comply with audits carried out by Delcath Systems, Inc., or a third party acting on behalf of Delcath Systems, Inc., to ensure that all training, processes, and procedures are in place and are being followed.

What does a healthcare setting need to do prior to administration of HEPZATO KIT?

Before administering, the authorized representative and/or healthcare setting staff must obtain authorization to dispense each HEPZATO KIT by contacting the REMS to verify the percutaneous hepatic perfusion procedure team is qualified using the **Procedure Team Qualification Status Form**

- The **Procedure Team Qualification Status Form** is used to document the dates each PHP team member completed their training and the dates of two prior procedures performed with HEPZATO KIT.
- The REMS will provide authorization for the healthcare setting to dispense HEPZATO KIT once the form is processed.
- If the **Procedure Team Qualification Status Form** is not received and these criteria are not met, the Healthcare Setting is not authorized to dispense HEPZATO KIT.

What does a healthcare setting need to do during and after administration of HEPZATO KIT?

During and after administering, for at least 72 hours, the healthcare setting must assess the patient for severe peri-procedural complications associated with HEPZATO KIT. If severe peri-procedural complications occur, the healthcare setting must document the adverse event using the **Severe Peri-Procedure-related Complications Adverse Events Documentation Form** and submit the form to the REMS.

All materials are available at www.HEPZATOKITREMS.com or by calling the REMS Coordinating Center at 1-833-632-0457.

Authorized Representatives can enroll online at www.HEPZATOKITREMS.com or by e-mail at coordinator@HEPZATOKITREMS.com