



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

A Patient's Guide to HEPZATO KIT

This is for informational purposes only and should not be considered medical advice.
Please consult with your physician to see if HEPZATO KIT is right for you.

What is HEPZATO and HEPZATO KIT?

HEPZATO (melphalan) is a prescription drug for liver-directed treatment for adults with uveal melanoma (a certain type of eye cancer) that has spread to the liver but can't be removed with surgery. This treatment is for cases where less than half of the liver is affected, and the cancer hasn't spread to other parts of the body, or it has only spread to the bones, lymph nodes, skin, or lungs where it can be treated with surgery or radiation.

HEPZATO KIT uses a special delivery system to send the medicine HEPZATO (melphalan) directly to the liver artery and a filtration system to reduce the amount of melphalan in the blood before it goes back into the rest of the body.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about HEPZATO?

- HEPZATO may cause serious problems like bleeding, liver damage, and blood clots. You may need to stop taking blood thinners or blood pressure medicine before treatment with HEPZATO KIT.
- HEPZATO can only be used through a special program called the HEPZATO KIT REMS (Risk Evaluation and Mitigation Strategies) Program.
- HEPZATO can lower the number of blood cells, leading to serious infections, bleeding, or anemia. Tell your doctor right away if you have a fever, bruising, or bleeding.

Please see additional IMPORTANT SAFETY INFORMATION throughout this brochure and [see here](#) for accompanying full Prescribing Information, including Boxed Warning.

This brochure will provide more information about HEPZATO KIT, so you and your oncologist can decide if this treatment is right for you.

Metastatic uveal melanoma and your liver

- **Uveal melanoma** (or eye cancer) that has spread to other parts of your body is called metastatic uveal melanoma
- **About half** of patients with uveal melanoma will develop metastatic uveal melanoma
- **In metastatic uveal melanoma, the liver is the most common location for metastases.** Some of these tumors that have spread to the liver will be visible on scans, but some may be too small to detect
- **If left untreated**, liver tumors could continue to grow and may lead to liver failure



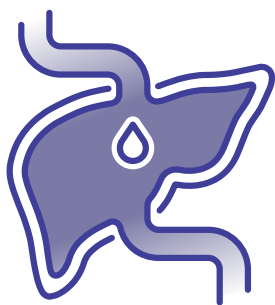
90% of patients with metastatic uveal melanoma tumors will develop tumors in the liver

Treating metastatic uveal melanoma

You have choices for treatment of metastatic uveal melanoma and liver tumors caused by metastatic uveal melanoma. Your oncologist will talk with you about them.

Please see additional IMPORTANT SAFETY INFORMATION throughout this brochure and [see here](#) for full Prescribing Information, including Boxed Warning.

What is HEPZATO KIT?



HEPZATO KIT, the first FDA-approved liver-directed therapy, is a drug-device combination that uses a special blood filtering system to deliver chemotherapy directly to your whole liver.

Unlike most IV infusion chemotherapy that delivers drugs into your bloodstream, this unique drug-delivery approach reduces the amount of chemotherapy reaching other parts of your body.

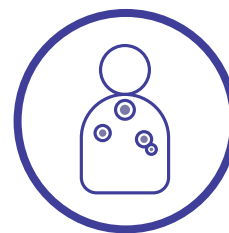
Eligible patients must include all of the following



Adults with uveal melanoma that has spread to the liver, with tumors that cannot be removed surgically



Adults with liver metastases occurring in less than 50% of the liver and the cancer has not spread to the rest of the body **OR**



Adults with uveal melanoma that has spread to bone, lymph nodes, skin, or the lungs, and these other tumors can be surgically removed or treated with radiation

IMPORTANT SAFETY INFORMATION

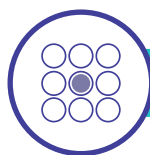
Do not take HEPZATO if you have:

- active brain cancer or brain spots that are likely to bleed
- liver failure, high blood pressure in the liver, or known risk of bleeding in the liver
- surgery or medical treatment of the liver in the past 4 weeks
- blood clotting problems that can't be fixed

Please see additional IMPORTANT SAFETY INFORMATION throughout this brochure and [see here](#) for full Prescribing Information, including Boxed Warning.

How does HEPZATO KIT work?

HEPZATO KIT is a **unique, 3-step delivery system** for a high-dose chemotherapy called **melphalan** (mel-fah-lan). Melphalan is a well-known, often-used, and effective chemotherapy medicine for people with cancer.



STEP 1: ISOLATION

Your liver's blood supply is temporarily separated from your body's blood supply using several small plastic tubes (also known as catheters). This "isolation" step is important because your liver will receive high-dose chemotherapy.



STEP 2: SATURATION

Once isolated, HEPZATO KIT delivers melphalan (HEPZATO) to your liver. This step lasts about 30 minutes and delivers high-dose chemotherapy to the tumors, detected and undetected.



STEP 3: FILTRATION

Once treatment is finished, the separated blood supply in your liver will be filtered for about 30 minutes before being returned to your body. This filtration step removes more than 80%* of the melphalan (HEPZATO).

*Mean (standard deviation) filter efficiency 82.7% (14.4%) for the total filtration period.

IMPORTANT SAFETY INFORMATION

Do not take HEPZATO if you have:

- inability to safely undergo general anesthesia, including heart problems like unstable or severe chest pain, heart attack, worsening or new heart failure, serious irregular heartbeats, or severe heart valve disease
- history of allergies or known reactions to melphalan or any part of the HEPZATO KIT, including natural rubber latex, heparin, or severe reactions to iodine contrast not controlled by antihistamines and steroids

Please see additional IMPORTANT SAFETY INFORMATION throughout this brochure and [see here](#) for full Prescribing Information, including Boxed Warning.

Proven results with HEPZATO KIT

HEPZATO KIT Effectiveness



A phase 3 clinical study of HEPZATO KIT included **91 patients** with metastatic uveal melanoma



More than **1/3** of patients (33) with metastatic uveal melanoma responded to treatment with HEPZATO KIT

- **7.7%** of patients had a complete response, which means that their tumors reduced in size and were able to be removed by surgery or disappeared completely
- **28.6%** had a partial response, which means that their target tumors reduced in size by 30% or more



In patients who had their tumors disappear or shrink, responses lasted for a median of **14 months**

70% of patients had a response that lasted at least or more than 6 months

30% of patients had a response that lasted at least or more than 12 months

*A response is a sum of partial response and complete response. Partial response is defined as a reduction in size of target tumors by 30% or more and complete response is defined as complete disappearance of all target tumors.

IMPORTANT SAFETY INFORMATION

The most common side effects of HEPZATO are: low platelets, tiredness, low red blood cells, nausea, muscle and bone pain, low white blood cells, belly pain, vomiting, high liver enzymes, longer blood clotting time, and shortness of breath. You can see the full list of potential side effects starting on page 14.

Immediately reach out to your oncologist if you experience any of the following side effects:



Fever, bruising, signs of bleeding



Skin rash, hives, itchiness



Shortness of breath, coughing, increased heart rate, dizziness

Other symptoms to report to your oncologist may include

- Nausea, vomiting, diarrhea
- Muscle pain, stomach pain
- Feeling more tired than usual

Please see additional IMPORTANT SAFETY INFORMATION throughout this brochure and [see here](#) for full Prescribing Information, including Boxed Warning.

How do I get started on HEPZATO KIT treatment?



Your first step toward treatment with HEPZATO KIT starts with your **oncologist**. They'll assess your metastatic uveal melanoma and your overall health to see if you're a candidate for HEPZATO KIT.

Your assessment will include lab tests, heart and liver function tests, CT or MRI scans, and other medical exams.



IMPORTANT SAFETY INFORMATION

HEPZATO may cause serious side effects including:

Secondary malignancies, HEPZATO could have a long-term risk of causing another type of cancer.

HEPZATO can cause serious birth defects if taken during pregnancy. Females who can become pregnant should use effective birth control during treatment with HEPZATO and for 6 months after the last dose. Contact your doctor if you become pregnant or think you might be pregnant while taking HEPZATO. Males with partners who can become pregnant should use effective birth control during treatment with HEPZATO and for 3 months after the last dose.

Infertility, HEPZATO has been reported to cause infertility in females and males.

Do not breastfeed during treatment with HEPZATO and for one week after the last dose.

The most common side effects of HEPZATO are: low platelets, tiredness, low red blood cells, nausea, muscle and bone pain, low white blood cells, belly pain, vomiting, high liver enzymes, longer blood clotting time, and shortness of breath.

Please see additional IMPORTANT SAFETY INFORMATION throughout this brochure and [see here](#) for full Prescribing Information, including Boxed Warning.

Before, during, and after HEPZATO KIT

What you need to know



Before the Procedure*

3 weeks before

- **Physical exam** and review of your medical history
- **Baseline tests** will be performed and may include
 - Blood tests
 - Liver function tests
 - Heart and lung evaluation
 - Other tests, as needed



2 weeks before

- **Baseline scans** to confirm the size and location of the tumor(s)
- Your **care team** will discuss possible procedure risks with you

1 week before

- You may be advised to **stop taking certain medications**
- You will be prescribed **pre-procedure medications**
- **Hydration** (fluid intake) instructions will be reviewed with you
- You will need to receive **pre-procedure clearance**

Day before treatment

- **Follow** the hydration instructions
- **Start** your prescribed pre-procedure medications

Continued on next page

*This is a general overview—these timelines/guidelines may vary and will depend on your condition, your doctor, and the facility guidelines.

Please see additional IMPORTANT SAFETY INFORMATION throughout this brochure and [see here](#) for full Prescribing Information, including Boxed Warning.

Before, during, and after HEPZATO KIT (cont.)



Day of Procedure and Post-procedure*

Procedure day

- Continue to take your prescribed **pre-procedure medications**
 - Bring other medications you are taking with you to the hospital
- Your **care team** will administer additional hydration before and medications during the procedure, as needed
- You will receive **general anesthesia** and will be monitored closely during the procedure
- The HEPZATO KIT procedure will take **approximately 3 hours**



Post-procedure and hospital stay

- **You will stay in the hospital** for at least one night and will be monitored for any complications for at least 72 hours after the procedure

Hospital discharge

- **Medication** may be prescribed for you to manage any side effects
- **If you are discharged** before 72 hours post-procedure, a follow-up with a member of your care team may take place virtually or over the phone

*This is a general overview—these timelines/guidelines may vary and will depend on your condition, your doctor, and the facility guidelines.

Continued on next page

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about HEPZATO?

- HEPZATO may cause serious problems like bleeding, liver damage, and blood clots. You may need to stop taking blood thinners or blood pressure medicine before treatment with HEPZATO KIT.

Please see additional IMPORTANT SAFETY INFORMATION throughout this brochure and [see here](#) for full Prescribing Information, including Boxed Warning.

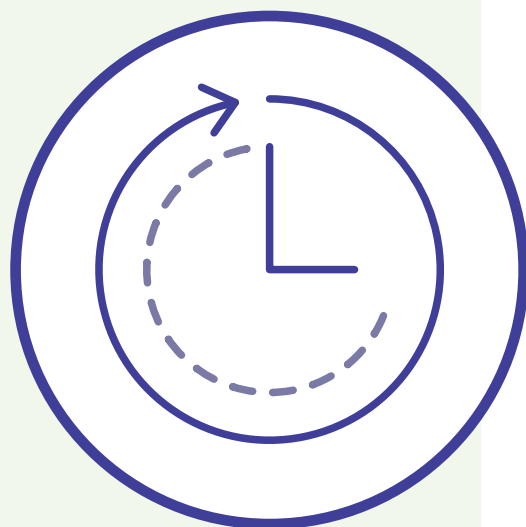
Before, during, and after HEPZATO KIT (cont.)



Continued Follow-up and Additional HEPZATO KIT Treatments*

Follow-up

- Your oncologist will continue to **follow-up and monitor** you (which may include additional scans)
- Your oncologist will **evaluate any need to stop or adjust current medications** and inform you of when you can return to your normal daily activities



Additional treatments

- If you and your oncologist agree, HEPZATO KIT may be repeated every **6 to 8 weeks** for up to **5 additional cycles**

*This is a general overview—these timelines/guidelines may vary and will depend on your condition, your doctor, and the facility guidelines.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about HEPZATO?

- HEPZATO can only be used through a special program called the HEPZATO KIT REMS (Risk Evaluation and Mitigation Strategies) Program.

Please see additional IMPORTANT SAFETY INFORMATION throughout this brochure and [see here](#) for full Prescribing Information, including Boxed Warning.

Who is part of the HEPZATO KIT procedural team?

Each member of your procedural team has completed extensive hands-on training and has been certified in the HEPZATO KIT REMS Program.



Interventional Radiologist

As procedure team leader, is responsible for image-guided catheter insertion (using minimally invasive small incisions to help reduce your recovery time) to isolate the liver blood supply and deliver the chemotherapy.



Perfusionist

Establishes, monitors, and controls the liver blood supply (using medical pumps) to be sure melphalan is properly introduced, circulated, and filtered before being put back into your body.



Anesthesiologist

Manages and monitors your sedation, breathing, and heart function during the procedure.

Your HEPZATO KIT procedural team will be supported by additional healthcare professionals.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about HEPZATO?

- HEPZATO can lower the number of blood cells, leading to serious infections, bleeding, or anemia. Tell your doctor right away if you have a fever, bruising, or bleeding.

Please see additional IMPORTANT SAFETY INFORMATION throughout this brochure and [see here](#) for full Prescribing Information, including Boxed Warning.

Who else is part of the HEPZATO KIT healthcare team?



Oncologist

Manages patient care and monitors chemotherapy side effects over the days following procedure



Pharmacist

Prepares and delivers chemotherapy to procedural room



Chemotherapist

Ensures chemotherapy is ready for use by interventional radiologist during procedure



Intensivist

Manages critical care patients and monitors patients immediately after procedure

IMPORTANT SAFETY INFORMATION

Do not take HEPZATO if you have:

- active brain cancer or brain spots that are likely to bleed
- liver failure, high blood pressure in the liver, or known risk of bleeding in the liver

Please see additional IMPORTANT SAFETY INFORMATION throughout this brochure and [see here](#) for full Prescribing Information, including Boxed Warning.

Questions to ask your oncologist and healthcare team about HEPZATO KIT



What are the risks associated with HEPZATO KIT?



Are there any dietary or medication restrictions before the procedure?



How is HEPZATO KIT different from other treatments I may have had for my uveal melanoma?



How long does it take to recover from the procedure? What type of follow-up is required?



How long would I have to wait after receiving a different treatment option before I might be eligible for treatment with HEPZATO KIT?



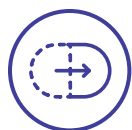
When can I go back to work? Normal activities?



What additional workups/imagings might be done before my procedure?



Will I still need to take other medicines for my eye cancer after I am treated with HEPZATO KIT?



What else should I know about what will happen to me during and after the HEPZATO KIT procedure?



Why might I need to receive HEPZATO KIT more than once?



Will I lose my hair?



How can I find a treatment center?



Is it safe to have filtered blood put back into my body?



Will my insurance cover HEPZATO KIT treatment?

IMPORTANT SAFETY INFORMATION

Do not take HEPZATO if you have:

- surgery or medical treatment of the liver in the past 4 weeks
- blood clotting problems that can't be fixed

Please see additional IMPORTANT SAFETY INFORMATION throughout this brochure and [see here](#) for full Prescribing Information, including Boxed Warning.

HEPZATO KIT Access 360 Program

Unlock streamlined support at every step of your treatment journey.

With **HEPZATO KIT™ ACCESS 360**, you're never alone. Our team helps you access financial relief, personalized guidance, and a smoother path to care—so you can focus on what matters most.

What We Offer

Financial Assistance

Eligible patients may pay as little as \$0, with up to \$10,000 in copay support per calendar year.

Dedicated Clinical Navigator

Get help navigating approvals, coordinating care, and answering questions from consult to follow-up.

Tailored Support

We personalize every step—matching guidance, financial aid, and care coordination to your needs.

Barrier-Free Access

We help remove roadblocks, manage paperwork, and simplify logistics to keep treatment on track.

Eligibility

You may qualify if you are:

- Commercially insured
- A U.S. resident treated with HEPZATO KIT™
- Receiving care at a Delcath REMS-certified facility

Get Started Today

Complete the [Enrollment and HIPAA forms](#) now

Questions? We're here to help.



1-866-4-HEPZATO



info@hepzatokitaccess.com



Monday-Friday 8 am-8 pm ET



hepzatokitaccess.com

Please see additional IMPORTANT SAFETY INFORMATION throughout this brochure and [see here](#) for full Prescribing Information, including Boxed Warning.

Important Safety Information

What is HEPZATO and HEPZATO KIT?

HEPZATO (melphalan) is a prescription drug for liver-directed treatment for adults with uveal melanoma (a certain type of eye cancer) that has spread to the liver but can't be removed with surgery. This treatment is for cases where less than half of the liver is affected, and the cancer hasn't spread to other parts of the body, or it has only spread to the bones, lymph nodes, skin, or lungs where it can be treated with surgery or radiation.

HEPZATO KIT uses a special delivery system to send the medicine HEPZATO (melphalan) directly to the liver artery and a filtration system to reduce the amount of melphalan in the blood before it goes back into the rest of the body.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about HEPZATO?

- HEPZATO may cause serious problems like bleeding, liver damage, and blood clots. You may need to stop taking blood thinners or blood pressure medicine before treatment with HEPZATO KIT.
- HEPZATO can only be used through a special program called the HEPZATO KIT REMS (Risk Evaluation and Mitigation Strategies) Program.
- HEPZATO can lower the number of blood cells, leading to serious infections, bleeding, or anemia. Tell your doctor right away if you have a fever, bruising, or bleeding.

Do not take HEPZATO if you have:

- active brain cancer or brain spots that are likely to bleed
- liver failure, high blood pressure in the liver, or known risk of bleeding in the liver
- surgery or medical treatment of the liver in the past 4 weeks
- blood clotting problems that can't be fixed
- inability to safely undergo general anesthesia, including heart problems like unstable or severe chest pain, heart attack, worsening or new heart failure, serious irregular heartbeats, or severe heart valve disease
- history of allergies or known reactions to melphalan or any part of the HEPZATO KIT, including natural rubber latex, heparin, or severe reactions to iodine contrast not controlled by antihistamines and steroids

HEPZATO may cause serious side effects including:

Secondary malignancies, HEPZATO could have a long-term risk of causing another type of cancer.

HEPZATO can cause serious birth defects if taken during pregnancy. Females who can become pregnant should use effective birth control during treatment with HEPZATO and for 6 months after the last dose. Contact your doctor if you become pregnant or think you might be pregnant while

Please see additional IMPORTANT SAFETY INFORMATION throughout this brochure and [see here](#) for full Prescribing Information, including Boxed Warning.

taking HEPZATO. Males with partners who can become pregnant should use effective birth control during treatment with HEPZATO and for 3 months after the last dose.

Infertility, HEPZATO has been reported to cause infertility in females and males.

Do not breastfeed during treatment with HEPZATO and for one week after the last dose.

The most common side effects of HEPZATO are: low platelets, tiredness, low red blood cells, nausea, muscle and bone pain, low white blood cells, belly pain, vomiting, high liver enzymes, longer blood clotting time, and shortness of breath.

Please see full Prescribing Information, including Boxed Warning.

Call your healthcare provider for medical advice about side effects. To report SUSPECTED ADVERSE REACTIONS, contact Delcath at 1-833-632-0458 and www.Delcath.com or FDA at 1-800-FDA-1088 or <http://www.fda.gov/medwatch>.

Please see additional IMPORTANT SAFETY INFORMATION throughout this brochure and [see here](#) for full Prescribing Information, including Boxed Warning.



Copyright © 2025 Delcath Systems, Inc. All rights reserved.
AMER-P-1469-v3(v3.0) 05/25

Please see additional IMPORTANT SAFETY INFORMATION throughout this brochure and [see here](#) for full Prescribing Information, including Boxed Warning.

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

16