

# Gilvetmab Frequently Asked Questions



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# General FAQs

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## **What is gilvetmab?**

Gilvetmab is a caninized anti-PD-1 monoclonal antibody that has received conditional approval for the treatment of dogs with stage I, II, or III mast cell tumor or stage II or III melanoma. It is the first commercially available immune checkpoint inhibitor in veterinary medicine.

## **How is gilvetmab supplied?**

Gilvetmab is available in cartons containing 10 single-use 3 mL vials at a concentration of 20 mg/mL.

## **How is gilvetmab administered?**

Gilvetmab is administered as an intravenous (IV) infusion of 4.5 mg/lb or 0.225 mL/lb (10 mg/kg or 0.5 mL/kg) body weight over at least 30 minutes. Administer manually or use a constant rate syringe pump.

## **How is gilvetmab stored?**

Gilvetmab should be stored upright at 2 - 8°C (35 - 46°F). Do not freeze.

## **Where is gilvetmab currently available?**

Gilvetmab is only available in the United States.

## **What is the shelf life of gilvetmab?**

The shelf life is 24 months after the manufacturing date.

## **How long can I use a vial once it has been punctured?**

Each vial is for single use only and any unused product should be discarded.

## **Who can I talk to if I have any questions about gilvetmab?**

If you have any questions, please call our Technical Services team at 1.800.224.5318.

# Oncologist FAQs

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## Safety & Efficacy

### What clinical information do you have about efficacy?

Gilvetmab has demonstrated a reasonable expectation of efficacy in reducing the solid tumor burden in dogs with stage I, II, and III mast cell tumors or dogs with stage II and III melanomas. In the initial trial of 26 client-owned dogs with mast cell tumor, 73% experienced a decrease in target lesion size or maintenance of stable disease. In the initial trial of 25 client-owned dogs with melanoma, 60% experienced a decrease in target lesion size or maintenance of stable disease.

### What clinical information do you have about safety?

Gilvetmab has demonstrated a reasonable expectation of efficacy and a preliminary safety profile in reducing the solid tumor burden in dogs with stage I, II, and III mast cell tumors or dogs with stage II and III melanomas. In a safety trial with 50 healthy beagle dogs, there were no treatment-related adverse events observed during the study with the exception of three dogs which displayed mild to moderate clinical signs consistent with an allergic reaction. All clinical signs resolved rapidly with treatment. These clinical signs reoccurred in one dog on the next treatment while the other 2 dogs did not display these clinical signs again on subsequent treatments. No other adverse events were noted over repeated infusions.

A field study demonstrated that gilvetmab is well tolerated in client-owned dogs with mast cell tumors or melanomas after IV infusion over at least 30 minutes. A total of 51 dogs enrolled in the study were evaluated for adverse events (AE). Dogs maintained a favorable quality of life as indicated during the study by >92% of owners of melanoma patients and 100% of owners of mast cell tumor patients.

For more complete information regarding safety, see [productdata.aphis.usda.gov](http://productdata.aphis.usda.gov).

### How is gilvetmab metabolized?

Gilvetmab is a monoclonal antibody that remains in circulation for several weeks. It exerts its effect by binding to its target receptor on canine CD4+ and CD8+ T lymphocytes. Like other naturally occurring antibodies, elimination is via normal protein degradation pathways.

### **Has gilvetmab been used in other cancers?**

Gilvetmab is currently only labeled for use in dogs with mast cell tumor stages I, II, and III or dogs with melanoma stage II or III. For veterinary oncologists interested in researching the utility of gilvetmab in other clinical scenarios, the Gilvetmab Product Grant Program provides product for use in clinical trials that may include, but are not limited to, investigation of the use of gilvetmab in other cancers, with adjunct therapies, and exploration of potential biomarkers of successful use. For full information about the Gilvetmab Product Grant Program, please visit [link](#).

### **Can gilvetmab be used with other melanoma treatments or mast cell tumor treatments?**

Gilvetmab has not been studied in combination with other therapies. For veterinary oncologists interested in researching the utility of gilvetmab in other clinical scenarios, the Gilvetmab Product Grant Program provides product for use in clinical trials that may include but are not limited to investigation of the use of gilvetmab in other cancers, with adjunct therapies, and exploration of potential biomarkers of successful use.

### **Do dogs experience pseudoproggression with gilvetmab?**

In preliminary studies, there were some dogs that showed clinical evidence consistent with pseudoproggression which was not confirmed with biopsy.

## Indications & Side Effects

### **What are the indications for use of Gilvetmab?**

Gilvetmab has demonstrated a reasonable expectation of efficacy and a preliminary safety profile in reducing the solid tumor burden in dogs with stage I, II, and III mast cell tumors or dogs with stage II and III melanomas.

### **Are there any contraindications?**

Gilvetmab use is contraindicated in dogs that have experienced evidence of hypersensitivity or severe adverse reactions.

Other immune-mediated adverse reactions: In patients with a history of previous autoimmune disease, consider the benefit of treatment with gilvetmab versus the risk of possible re-emergence of autoimmune disease.

## How do I determine whether a dog is a candidate for gilvetmab?

Any dog with stage I, II, and III mast cell tumor or dogs with stage II and III melanoma could be considered a candidate for gilvetmab use. Patients requiring immunosuppressive therapy for any reason are not candidates for treatment with gilvetmab. The use of gilvetmab with concurrent adjunct therapeutics (e.g., chemotherapy, radiation therapy, targeted therapy, etc.) for treatment of cancer has not been evaluated.

## What are the side effects from treatment?

During field studies, patients maintained a good quality of life. Adverse reactions were generally transient, including mainly lethargy, inappetence or gastrointestinal upset. Serious reactions were uncommon. In the laboratory safety studies, some dogs did experience reactions during administration which were typically mild. Facial, eye or ear swelling, and local reddening were most common. Please see the [Product Insert](#) for more information.

## Mechanism of Action

### What is the mechanism of action of gilvetmab?

Gilvetmab is a checkpoint inhibitor. Checkpoint inhibitors are monoclonal antibodies that help T cells fight cancer. The antibodies do not target the cancer specifically, rather they prevent the cancer from turning off the immune system.

More specifically, gilvetmab is a checkpoint inhibitor that targets the PD-1 receptor on T cells. Binding of PD-1 to its ligands (PD-L1 or PD-L2) can result in inhibition of the T cell's ability to destroy the cancer. Gilvetmab prevents PD-1 on the T cell from interacting with the PD-L1 or PD-L2 ligands that can be found on some types of tumor cells or in the microenvironment surrounding a tumor.

## Other Questions

### Is there a PD-L1 test for dog?

There is currently no commercially available PD-L1 test available for dogs nor has the impact of PD-L1 positivity been evaluated for impact of responsiveness.

### Is there any prep required before treatment? For example, should dog be fasted? any pre-medications? etc.

Pretreatment with diphenhydramine 2 mg/kg intramuscular (IM) within 15-30 minutes of treatment is recommended.

## How can I order Gilvetmab?

Gilvetmab is available for purchase exclusively by board certified veterinary oncologists in the United States. Merck Animal Health is managing the launch and distribution of gilvetmab via its direct ordering and order fulfillment platform. For information on how to set-up an account, click [here](#).

# General Practitioner FAQs

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## Safety & Efficacy

### How does gilvetmab work?

Gilvetmab is a checkpoint inhibitor that works by blocking PD-1 on the T cell from interacting with programmed cell death ligand 1 (PD-L1) on the cancer. This allows T cells to regain their ability to kill cancer cells.

### What are the clinical trial results of Gilvetmab?

In the initial trial of 26 client-owned dogs with mast cell tumor, 73% experienced a decrease in target lesion size or maintenance of stable disease. In the initial trial of 25 client-owned dogs with melanoma, 60% experienced a decrease in target lesion size or maintenance of stable disease. Adverse events in these patients were primarily mild in nature.

### Should I be monitoring bloodwork? What should I expect?

There are no specific blood tests recommended with regard to gilvetmab.

## Indications & Side Effects

### For which dogs is gilvetmab indicated?

Gilvetmab is currently indicated for dogs with stage I, II, and III mast cell tumor or dogs with stage II and III melanoma. Dogs should not be currently receiving glucocorticoids or any other type of immunosuppressive medication (e.g., cyclosporine, etc.) when gilvetmab is used.

### How long is the treatment protocol for gilvetmab?

Gilvetmab is administered over 30 minutes using an intravenous catheter and diphenhydramine needs to be administered intramuscularly 15-30 minutes prior (unless the veterinary oncologist prescribes pills at home). It is also recommended that the dog be monitored for 1 hour after the infusion is completed for immediate side effects. Additional time may be required for any other testing the veterinary oncologist may deem necessary. This means that treatment will take at least 2 hours.

Gilvetmab is labeled for use every 2 weeks for up to 10 treatments, however, extended duration of use is at the discretion of the veterinary oncologist and may be appropriate in some cases.

### **What are the side effects of gilvetmab?**

During clinical field studies, patients maintained a good quality of life. Adverse reactions in the clinical trial were generally transient – including mainly lethargy, inappetence or gastrointestinal upset. Serious reactions were uncommon. In our laboratory safety studies, some dogs did experience reactions during administration which were typically mild. Facial, eye or ear swelling, and local reddening were most common.

If a patient receiving gilvetmab experiences unexplained changes in clinical signs or bloodwork (e.g., not obviously explained by the primary tumor or a pre-existing condition, etc.), it is recommended to contact the patient’s veterinary oncologist. Though not seen in our clinical trials, checkpoint inhibitors are known to cause immune-related adverse events in people.

### **What is pseudoprogression and why could I see it with a dog receiving gilvetmab?**

Tumor pseudoprogression is a phenomenon caused by immune checkpoint inhibitors where, likely due to the influx of immune cells into the tumor, the tumor gets bigger prior to involution. This phenomenon of pseudoprogression is well documented in human medicine. Some dogs treated with gilvetmab in the clinical trial showed clinical evidence consistent with pseudoprogression which was not confirmed with biopsy.

### **Are there any medications that are not recommended to be administered or prescribed if a pet is receiving gilvetmab?**

Dogs should not be currently receiving glucocorticoids or any other type of immunosuppressive medication (e.g., cyclosporine, etc.) when gilvetmab is used.

## Other General Practitioner Questions

### **Are there recommendations for timing of vaccination with gilvetmab administration?**

Preventative care is important for your every pet, including those undergoing cancer treatment. Concurrent vaccination and gilvetmab treatment has not been studied in dogs. In humans receiving checkpoint inhibitors, vaccination with inactivated vaccines is not contraindicated.

### **What oncologist(s) near me are using this product?**

Gilvetmab is available to all board-certified veterinary oncologists in the United States. Please click [here](#) to see a listing of veterinary oncologists.

### **There are no oncologists in my area. How can I get access to the product?**

Currently, gilvetmab is only available to board-certified (ACVIM or ECVIM) veterinary oncologists and a Veterinarian-Client-Patient-Relationship (VCPR) with a veterinary oncologist is required for treatment.



# Pet Owner FAQs

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## Safety & Efficacy

### How does gilvetmab work?

Gilvetmab is an immunotherapy that uses the immune system to help detect and fight cancer. Gilvetmab works to stop cancer cells from hiding and may enable the immune system to find and attack cancer cells.

### What can I expect from my dog while s/he is receiving gilvetmab?

A majority of dogs studied maintained a good quality of life while receiving gilvetmab. Adverse effects were generally mild and may also be associated with the primary cancer (e.g., lethargy, poor appetite, etc.). Because gilvetmab may take up to 1-2 months to work against the cancer, you may not see immediate changes in your pet's condition after starting treatment with gilvetmab.

### When in the course of treatment will we know if it's working for my dog?

The onset of effect is typically within 1-2 months. It is possible that your dog might actually experience an initial period of increase in size of the original tumor or new tumors within that same time frame as part of the response to gilvetmab. Your veterinary oncologist may recommend tests (i.e., a biopsy) to confirm that the increase in size is due to an appropriate response to gilvetmab versus tumor progression and resistance to gilvetmab. If the increase in tumor size is due to an appropriate response to gilvetmab, it is recommended to continue gilvetmab therapy.

## Indications & Side Effects

### For which dogs is gilvetmab indicated?

Gilvetmab is currently indicated for dogs with stage I, II, and III mast cell tumor or dogs with stage II and III melanoma.

### What side effects will the treatment have?

In the field trial, pet owners indicated that their dogs maintained a good quality of life. Side effects included being tired, loss of appetite or stomach upset. These effects generally did not last long. More serious reactions were not commonly seen. Some dogs may develop mild reactions, such as face, eye or ear swelling or reddening at the injection site.

### **Does gilvetmab interact with other medications?**

There are no known interactions with other medications though this was not specifically studied. Medications, such as corticosteroids, that decrease or inhibit how well the immune system works could decrease the efficacy of gilvetmab.

### **What should I be monitoring at home?**

The most common signs to look for once your dog has been discharged are being tired, not eating or stomach upset (i.e., vomiting or diarrhea). You should also watch for redness or swelling at the location where the catheter was inserted. Report any evidence of facial swelling or other possible side effects to your veterinarian.

## Other Pet Owner Questions

### **How long will the treatment take and how often will I have to bring my dog in for treatment?**

Gilvetmab is administered over 30 minutes using an intravenous catheter and diphenhydramine (i.e., Benadryl) needs to be administered intramuscularly 15-30 minutes prior (unless your veterinarian prescribed pills at home). It is also recommended that your dog be monitored for 1 hour after the infusion is completed for immediate side effects. Additional time may be required for any other testing your veterinary oncologist may deem necessary. This means that treatment will take at least 2 hours. Your veterinary oncologist will determine the appropriate frequency of the treatment schedule for your dog.

### **Is my dog sedated during the treatment?**

Sedation is not required for gilvetmab infusion unless your oncologist believes your dog's temperament is such that it may be required for compliance with the infusion.

### **Can dogs continue taking holistic treatments concurrently with gilvetmab?**

Gilvetmab has not been studied in combination with holistic treatments. Talk to your veterinary oncologist about the types of holistic treatments your pet is receiving.

### **How much will it cost for my dog to be treated?**

There are many factors that influence how much it will cost for your dog to be treated with gilvetmab, including the size of your dog, how long he or she is treated, and other costs associated with administering the treatment. Talk to your veterinary oncologist about an estimated cost of treatment with gilvetmab.

### **Are there any programs that assist with costs?**

Merck Animal Health does not have programs to assist with the cost of gilvetmab treatment at this time. However, many programs exist to financially assist pet owners of dogs with cancer and can be found via an internet search or by asking your veterinary oncologist.