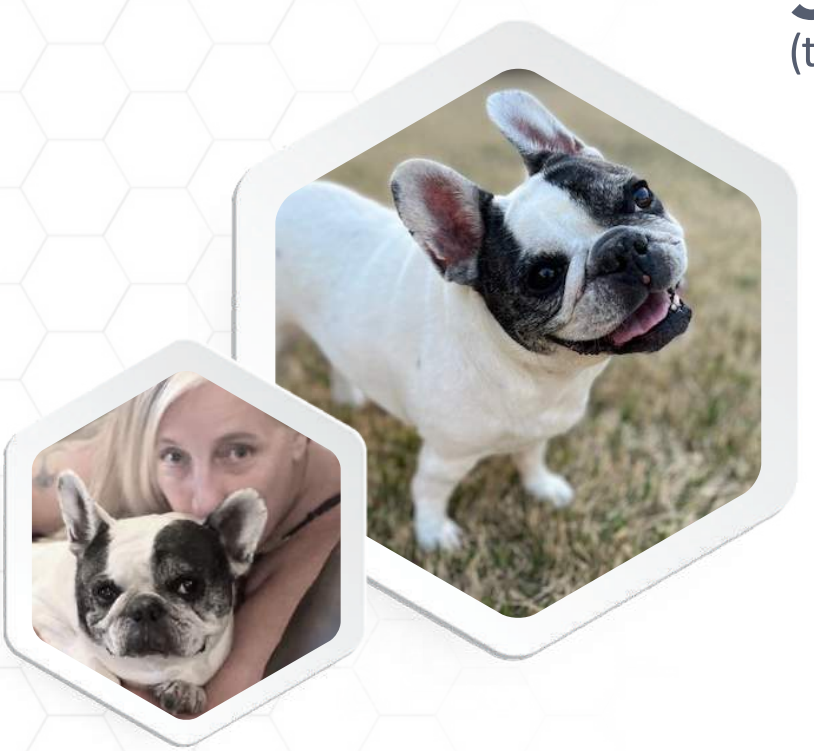
STELFONTA®
(tigilanol tiglate injection)



THE OPTION PET OWNERS PREFER[1]

See for yourself why veterinarians and pet owners are choosing STELFONTA® (tigilanol tiglate injection) to treat mast cell tumors (MCTs).

Virbac Shaping the future of animal health

STELFONTA® (tigilanol tiglate injection) "SEEING IS BELIEVING" SURVEY[1]

Veterinarians and pet owners were asked to share their experiences about treatment with STELFONTA, and the results were illuminating.

PARTICIPANTS

29 Veterinarians

30 Pet Owners

PATIENTS

44 Patients
A wide range of breeds

1-15 Years Old

0.1 cm–10.0 cm Tumor Volume
Trunk most common tumor location

How Pet Owners Feel About STELFONTA

Wound healing via second intention with minimal intervention*

STELFONTA promotes complete healing of the wound site, typically with minimal intervention and minimal scarring.[2] In most cases, pet owners didn't have to worry about changing bandages or confining their dogs in Elizabethan collars.

84% pet owners satisfied with the healing process.[1]

Meet Lori & Honey

There was nothing we had to do but make sure she got her medication and communicate with our veterinarian.

Honey is an 11-year-old Golden Retriever. Knowing one of their other dogs was having surgery and caring for both would be difficult, their veterinarian recommended STELFONTA as a good treatment option for Honey's nonmetastatic MCT.

Appropriate pre- and post-treatment medications must be administered in order to decrease the potential for severe systemic adverse reactions, including death, from mast cell degranulation.

Meet Olga & Lila

My experience was really good. If there was anything weird, I would ask, and my veterinarian would tell me if it was normal or not. It was really fast and was almost like it was melting away or consuming itself. And even though we talked about everything, I wasn't quite prepared for it to fall off!

10-year-old mutt Lila had a nonmetastatic MCT that was successfully treated with STELFONTA.

Treatment with STELFONTA has been associated with cellulitis and severe tissue sloughing extending away from the treated site, resulting in extensive wounds that require additional treatment and prolonged recovery time.

*Minimal intervention: Antibiotics, bandages and e-collars aren't usually required.

Alternative for Pet Owners with Surgery Concerns

This innovative treatment provides an alternative for pet owners who are concerned about anesthesia and surgery.

Meet Ally and Dixie

My husband did some research and learned about STELFONTA. We ended up finding a different veterinarian who was willing to try it. Dixie went through the procedure beautifully without sedation.

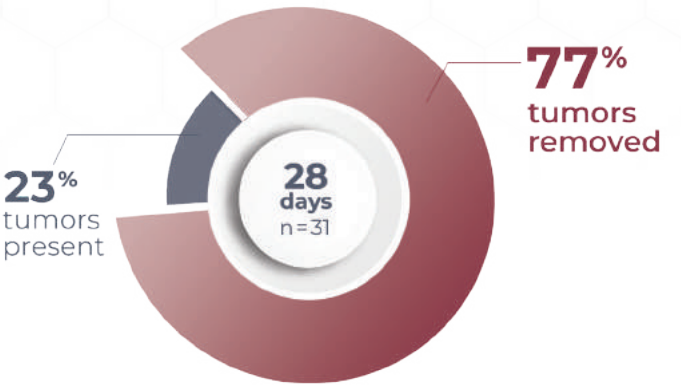
Dixie was diagnosed with a mast cell tumor when she was 7 years old. Due to the location, her veterinarian did not think they could operate and achieve the necessary margins — alternative options were radiation therapy or amputation of the limb.

To decrease the risk of accidental self-injection, sedation of the dog may be necessary.

Improved Quality of Life

STELFONTA helps pets and their owners return to the activities they love.

77% of pet owners reported that STELFONTA removed their dog's tumor by day 28.[1]



Meet Mary & Dale

The second day her leg swelled up, but I looked it up and that could be normal. And within a day it went down, and she just went along with it. And even when her leg was swollen, it didn't seem to bother her. She wasn't sleepy. She continued on with her activities.

Dale, a 12-year-old Basset/Beagle mix, was diagnosed with an MCT. Her owner, Mary, did some research and accepted her veterinarian's recommendation to try STELFONTA.

Ensure that all concomitant medications are administered as required and consider appropriate pain control as needed.

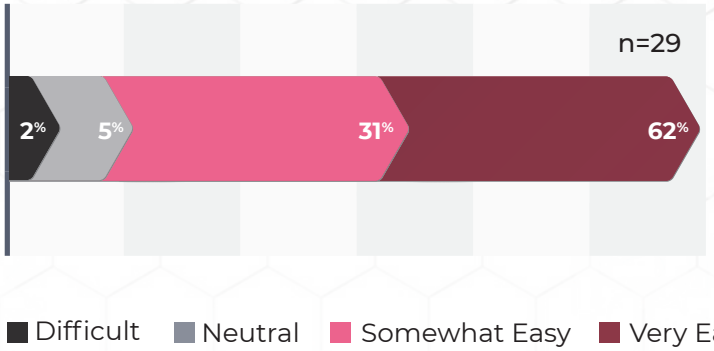
How Veterinarians Feel About STELFONTA

Veterinarians who have used STELFONTA are encouraged by the ease of use and excellent patient outcomes.

Easy to Administer

STELFONTA is easy to administer, and most dogs only require a single injection.[1]

Veterinarians found STELFONTA easy to use in 93% of patients.[1]



> *Treating a pet with STELFONTA is as easy as doing a fine needle aspirate to diagnose the mast cell tumor. It rarely requires sedation of the patient. The clients love that anesthesia or e-collars are virtually never needed.*
>
> **Erin Bendick, DVM**
> Owner and Veterinarian
> at Moultrie Animal Clinic

To decrease the risk of accidental self-injection, sedation of the dog may be necessary. Concomitant administration of a corticosteroid, an H1 receptor blocking agent and an H2 receptor blocking agent is required when treating with STELFONTA to decrease the potential for severe systemic adverse reactions, including death, from mast cell degranulation.

First-Line Treatment

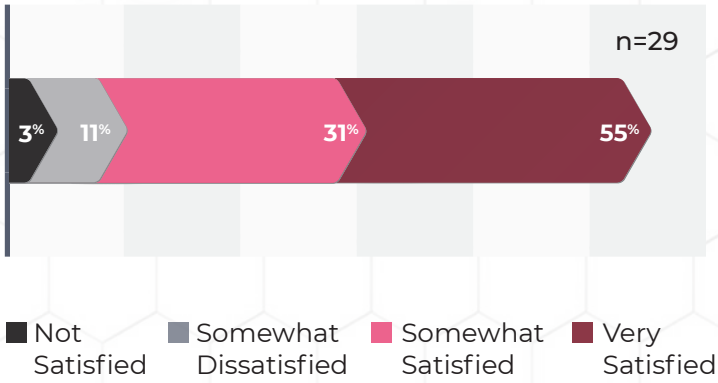
More and more veterinarians are offering STELFONTA as an option for effective, first-line treatment of MCTs.

100% veterinarians surveyed will continue to use STELFONTA and would also recommend it to their peers.[1]

> *I have found STELFONTA to be a product that engages clients, and they become impressed watching it work before their eyes. It is one of the only products that mitigates some of the fear following a cancer diagnosis. I have and will continue to recommend STELFONTA for mast cell tumors that fall within the usage guidelines.*
>
> **Jerrod Johnson, DVM**
> Co-owner, Gateway Animal Care Group

Overall Satisfaction

86% of veterinarians were satisfied with the overall treatment experience.[1]

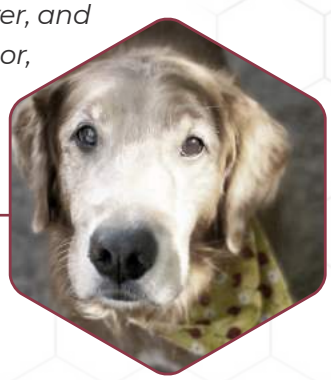


Jamie Rauscher, RVT

2022 President-Elect of the National Association of Veterinary Technicians in America

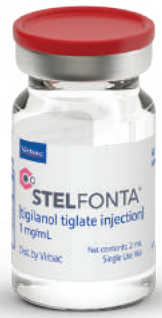
We have been happy with it. Owners have done well with it. I have a 13-year-old Golden Retriever, and if she had a mast cell tumor, I think that I would do it, just to not put her through surgical recovery.

Jamie would choose STELFONTA to treat her dog.



Formation of wounds, possibly extensive, is an intended and likely response to treatment with STELFONTA, along with the associated swelling, bruising and pain; these wounds are expected to heal.

For more and more veterinarians, seeing really is believing. Dogs who undergo treatment with STELFONTA typically heal within 28 days and return to their happy, active lives. Pet owners are relieved to have an alternative to surgery that allows their dogs to recover in the comfort of their own home.



See what a difference STELFONTA makes while earning CE credits.
View the e-learning modules at https://vet-us.virbac.com/stelfonta or scan here.

To place an order, contact your Virbac representative or call 1-844-4-VIRBAC (1-844-484-7222).

For case consultation, contact our Product Safety and Consulting Team at 1-800-338-3659. Visit https://vet-us.virbac.com/stelfonta for more information.

References: 1. Data on file, Virbac Corporation. **2.** Reddell P, De Ridder TR, Morton JM, et al. Wound formation, wound size, and progression of wound healing after intratumoral treatment of mast cell tumors in dogs with tigilanol tiglate. *J Vet Intern Med.* 2021;35(1):430–441. **3.** US STELFONTA packaging insert. [2020]

Virbac Shaping the future of animal health

Brief Summary: Before using STELFONTA® (tigilanol tiglate injection) consult the product insert, a summary of which follows:

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

WARNING: SEVERE WOUND FORMATION IN HUMANS; EXTENSIVE WOUND FORMATION, MAST CELL DEGRANULATION, AND DEATH IN DOGS DUE TO MAST CELL DEGRANULATION

Human Safety

- **Accidental self-injection of STELFONTA® may cause severe wound formation. To decrease the risk of accidental self-injection, sedation of the dog may be necessary (see Dosage and Administration, Human Warnings and Adverse Reactions on the product insert).**

Dog Safety

- **Always administer a corticosteroid (e.g. prednisone or prednisolone), an H1 receptor blocking agent (e.g. diphenhydramine), and an H2 receptor blocking agent (e.g. famotidine) when treating with STELFONTA to decrease the potential for severe systemic adverse reactions, including death, from mast cell degranulation (see Contraindications and Dosage and Administration on the product insert).**
- **Do not inject STELFONTA into subcutaneous mast cell tumors located above the elbow or hock (e.g. on the body, head, or neck). This may result in accumulation of necrotic debris in the subcutaneous space increasing the risk of systemic adverse reactions, including death, from mast cell degranulation (see Contraindications, Warnings and Adverse Events on the product insert).**
- **Treatment with STELFONTA has been associated with cellulitis and severe tissue sloughing extending away from the treated site resulting in extensive wounds that require additional treatment and prolonged recovery times (see Warnings, Precautions and Adverse Events on the product insert).**

Indications: STELFONTA injection is indicated for use in dogs for the treatment of:

- non-metastatic subcutaneous mast cell tumors located at or distal to the elbow or the hock
- non-metastatic cutaneous mast cell tumors

Concurrent Medications: Administer the following medications to decrease the potential for severe systemic adverse reactions from mast cell degranulation:

- **Corticosteroid (e.g. oral prednisone or prednisolone at anti-inflammatory dose):** Start medication 2 days prior to STELFONTA treatment and continue for 8 days post-treatment (10 days total).
- **H1 receptor blocking agent (e.g. oral diphenhydramine):** Start medication on the day of STELFONTA treatment and continue for a total of 8 days.
- **H2 receptor blocking agent (e.g. oral famotidine):** Start medication on the day of STELFONTA treatment and continue for a total of 8 days.

Dosing Instructions: STELFONTA is injected into the tumor at a dose of **0.5 mL per cm³** of tumor volume, as determined by measuring the tumor and calculating the dose based on **0.5 x length x width x height.**

The Tumor Volume is not to exceed 10 cm^3. The dose of STELFONTA is not to exceed 0.25 mL/kg body weight. The dose is not to exceed 5 mL per dog, regardless of tumor volume or body weight. The minimum dose of STELFONTA is 0.1 mL, regardless of tumor volume or body weight. If the calculated dose is <0.1 mL, administer 0.1 mL.

Contraindications: Do not inject STELFONTA into subcutaneous mast cell tumors located above the elbow or hock (e.g. on the body, head, or neck). This may result in accumulation of necrotic debris in the subcutaneous space increasing the risk of systemic adverse reactions, including death, from mast cell degranulation (see Adverse Reactions on the product insert).

WARNINGS: NOT FOR USE IN HUMANS. KEEP THIS AND ALL MEDICATIONS OUT OF REACH OF CHILDREN.

Caution is required during treatment to avoid accidental self-injection. Dogs undergoing treatment with STELFONTA should be adequately restrained and sedation used if necessary. People with known hypersensitivity to tigilanol tiglate or to any of the excipients should avoid contact with STELFONTA.

Wear disposable gloves when cleaning the treated tumor site to avoid contact with any residual drug. Thoroughly wash your skin that comes in contact with the treated tumor site, wound, or wound discharge.

STELFONTA may cause side effects, even at the prescribed dose. Ensure the dog receives their prescribed medications to decrease the potential for severe, life-threatening side effects from mast cell degranulation. Counsel owners to monitor the dog during the healing process and contact their veterinarian if they notice excessive pain, lameness, tiredness, refusal to eat for more than one day, repeated vomiting or diarrhea, trouble breathing, changes to the treated tumor site (including increased or excessive swelling and bruising, extensive wound formation, increased irritation) or any other symptoms that concern them.

PRECAUTIONS: STELFONTA® (tigilanol tiglate injection) has not been evaluated in dogs with signs of systemic disease due to the mast cell tumor(s).

STELFONTA is not intended for the treatment of metastatic mast cell tumors. The safe and effective use of STELFONTA has not been evaluated for simultaneous treatment of more than one mast cell tumor. The safe and effective use of STELFONTA has not been evaluated in dogs with a mast cell tumor volume >10 cm^3.

Use STELFONTA with caution in tumors located within mucocutaneous regions (e.g., eyelids, vulva, prepuce, and anus) as tumor necrosis could cause a change in morphology of the mucocutaneous region resulting in loss of functional integrity.

Use STELFONTA with caution in mast cell tumors with significant ulceration as leakage of the drug from the ulcerated area may occur following treatment potentially reducing effectiveness.

The safe use of STELFONTA has not been evaluated in dogs with concurrent diseases that may result in delayed wound healing. After treatment with STELFONTA, dogs may require additional care of the treated site to aid in the healing process. An Elizabethan collar or a non-constricting dry gauze bandage may be needed to prevent the dog from self-traumatizing the treated site.

After treatment with STELFONTA, separation from other household animals may be necessary to prevent grooming and trauma to the treated site.

The safe use of STELFONTA under conditions of use has not been evaluated in dogs younger than 3.5 years old.

The safe use of STELFONTA has not been evaluated in dogs that are pregnant, lactating, or intended for breeding.

Adverse Reactions: In a field study, the most common adverse reactions seen out of 117 dogs included wound formation (94%), injection site pain (52.1%), lameness in the treated limb (24.8%), vomiting (20.5%), diarrhea (20.5%), and hypoalbuminemia (18%). Wound formation, vomiting, and diarrhea were mainly observed within the first 7 to 10 days after treatment. Injection site pain and lameness in the treated leg were mainly observed within the first 2 days after treatment. Hypoalbuminemia was mainly observed within the first 28 days after treatment. All dogs received concomitant medications as noted in the Effectiveness section of the product insert.

Wound Formation

Tumor observations were conducted at 2, 4, 8, and 24 hours and 4 days after treatment. The 81 dogs treated with STELFONTA on Day 0 were reported most frequently with swelling, bruising, pain and heat at all tumor observation timepoints. The following were reported at 24 hours post treatment:

- Swelling: 97.5% (79/81 dogs)
- Bruising: 91.4% (74/81 dogs)
- Pain: 69.1% (56/81 dogs)
- Heat: 53.1% (43/81 dogs)

At 24 hours post treatment, intact skin was reported in 71.6% (58/81 dogs) of STELFONTA treated dogs. On Day 4 intact skin was reported in 17.3% (14/81 dogs) of STELFONTA treated dogs. On Day 4, the following observations were reported with the highest frequency:

- Necrosis: 55.6% (45/81 dogs)
- Crater pockets: 37.0% (30/81 dogs)
- Exudate: 37.0% (30/81 dogs)
- Eschar: 28.4% (23/81 dogs)
- Ulceration: 11.1% (9/81 dogs)

A wound healing assessment was performed on the effectiveness dataset which included 80 dogs in the STELFONTA group and 38 dogs in the untreated control group. Wounds developed in 92.5% (74/80) of STELFONTA treated dogs and 2.6% (1/38) of untreated control dogs by Day 7. On Day 28, the presence of wounds was 40% (32/80) in the STELFONTA group and 2.6% (1/38) in the untreated group. On Day 42 and Day 84, the presence of wounds was 27.1% (16/59) and 1.8% (1/57), respectively, in the STELFONTA group.

Effectiveness: See full prescribing information for details on effectiveness.

Contact Information: To report suspected adverse reactions, to obtain a Safety Data Sheet (SDS), or for technical assistance or case consultation, call 800-338-3659. For additional information about adverse drug experience reporting for animal drugs, contact the FDA at 1-888-FDA-VETS or www.fda.gov/reportanimalae.

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Fort Worth, Texas 76161
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