STELFONTA®
(tigilanol tiglate injection)

SEEING IS BELIEVING

"Single-injection mast cell tumor destruction?

I didn't believe it, until I saw it myself."

Dr Melissa Wiest,
Veterinarian

Always administer the recommended concomitant medications with STELFONTA.

Virbac Shaping the future of animal health

An innovative way to treat mast cell tumors (MCTs) in dogs

STELFONTA® (tigilanol tiglate injection) is an intratumoral injection indicated for use in dogs for the local treatment of MCTs that are:

Subcutaneous— located at, or distal to, the elbow or the hock

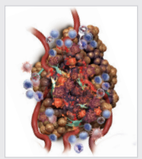
Cutaneous— located all over the body

STELFONTA should not be injected into subcutaneous mast cell tumors located above the elbow or hock (eg, on the body, head, or neck) as 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.

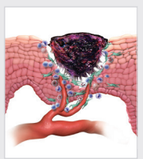
STELFONTA starts working within 2 hours,[1] with tumors typically destroyed by Day 7

Before treatment

4 Hours
An acute inflammatory response is observed with swelling and erythema to the tumor margins and immediate surrounding tissues[2]



Day 1–3
Increased permeability of tumor vasculature, induced by PKC ßII activation



Day 1–7
Tumor necrosis

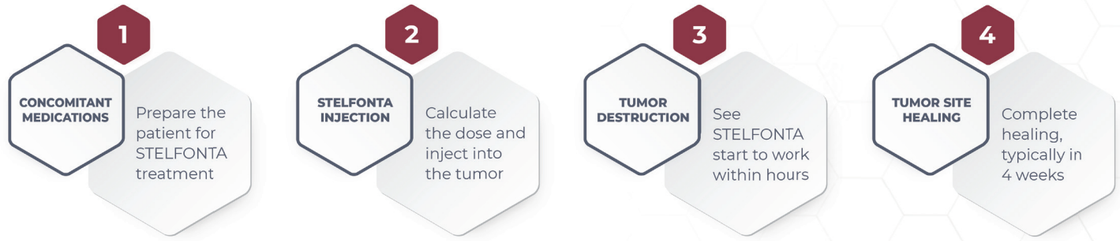
1 Week
Full tumor destruction leaving a "pocket" or wound where the tumor once was[2]

6 Weeks
Complete response; site fully "healed": Healthy new skin will grow and close over the pocket where the tumor once was[2]

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 case consultation and prescribing information, contact our Veterinary Technical Support Team at 1-800-338-3659. Visit https://vet-us.virbac.com/stelfonta for more information.

4 stages to treat MCTs with STELFONTA®



COMPLETE WOUND HEALING
usually occurs within 28–84 days.[3] Consider analgesics for pain management. There may be increased cellulitis, bruising, pain, and larger wound formation in some patients, requiring additional treatment.

Calculate the dose and inject STELFONTA directly into the tumor

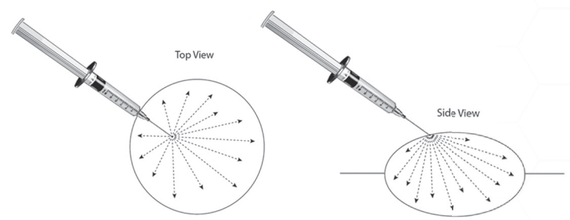
To administer STELFONTA[2]:

1. Accurately measure the length, width, and height of the tumor (in cm).

2. Determine the volume of the tumor: Volume of tumor (cm^3) = **½** x [length (cm) x width (cm) x height (cm)].

3. Then determine the correct dose: Dose (mL) = tumor volume (cm^3) x **½**.

- Confirm the dose of STELFONTA does not exceed 0.25 mL/kg body weight.
- Do not 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.



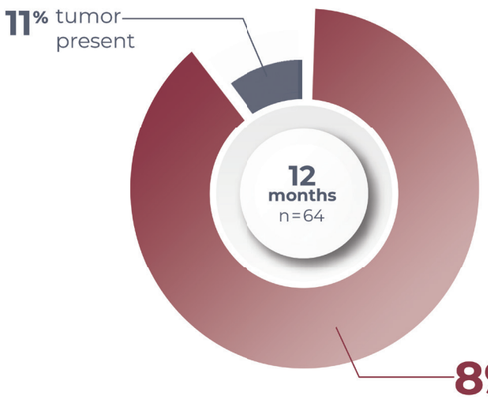
To decrease the risk of accidental self-injection, sedation of the dog may be necessary. Accidental self-injection of STELFONTA may cause local inflammation and wound formation.

STELFONTA®
(tigilanol tiglate injection)

STELFONTA® (tigilanol tiglate injection) removes 75% of MCTs with a single treatment[4]

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.

In a separate longitudinal study,[5] 89% of dogs achieving initial complete response* were still disease-free† at month 12



Sixty-four dogs were available for assessment at 12 months after initial complete response to STELFONTA. Fifty-seven dogs (89%) had no evidence of local MCT recurrence.[2]

*Complete response was defined as complete removal of the tumor.[4]
†No evidence of tumor recurrence at the site of STELFONTA treatment

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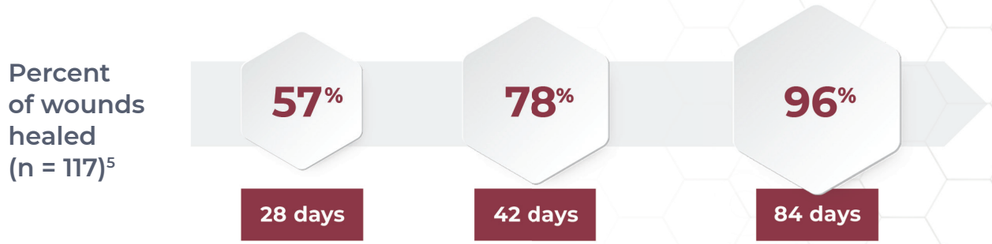
Second-intention healing with more than half of tumor sites fully healed by Day 28[3]



In a controlled clinical study[3]:

- Antibiotics were not prescribed in most cases (70/117)
- Only 1 of 117 dogs used an Elizabethan collar
- Only 1 of 117 dogs was bandaged

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.

STELFONTA®
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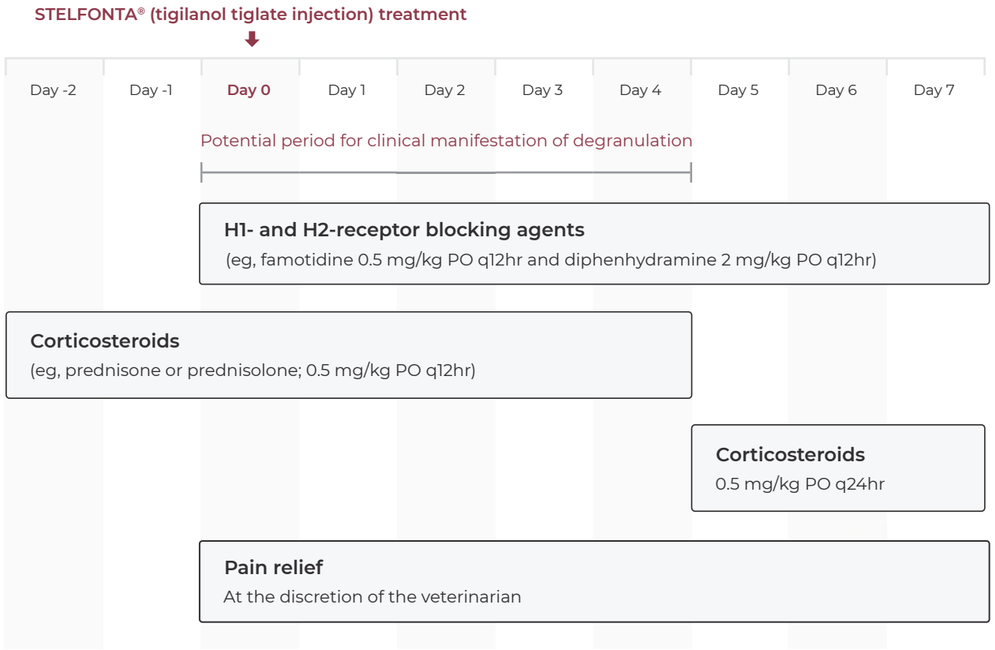
Concomitant medication dosing schedule[2]



q12hr: twice a day; **PO:** by mouth; **q24hr:** once a day

Always administer a corticosteroid (eg, prednisone or prednisolone), an H1-receptor blocking agent (eg, diphenhydramine), and an H2-receptor blocking agent (eg, famotidine) when treating with STELFONTA® (tigilanol tiglate injection) to decrease the potential for severe systemic adverse reactions, including death, from mast cell degranulation.

Reassure pet owners by letting them know what to expect

Ensure
owners give the concomitant medications as prescribed.

Explain
to pet owners what to expect at each stage. Refer clients to STELFONTA pet owner brochure and video for more information.

Observe
second-intention healing and regularly monitor the healing process.

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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 cm³. 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 cm³.

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.

Approved by FDA under NADA # 141-541

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See STELFONTA® (tigilanol tiglate injection) in action

Case summary

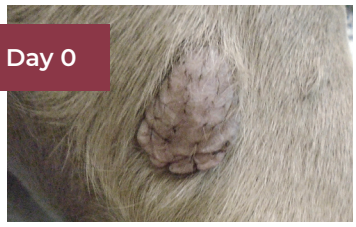
- 12-year-old, mixed breed, male dog (82 lbs)
- Cutaneous, nonmetastatic MCT on thigh

Treatment

Tumor volume: 2.7 cm^3
Tumor size: 1 x 3 x 1.8 cm
Calculated dose: 1.4 mL (0.038 mg/kg)

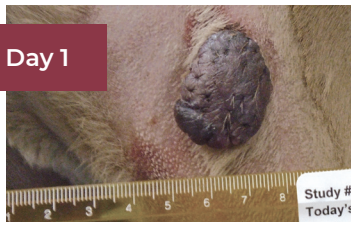
Complete response achieved with 1 treatment and second-intention healing

Day 0



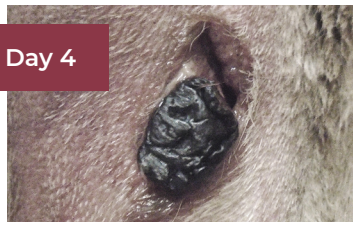
- MCT on the right thigh

Day 1



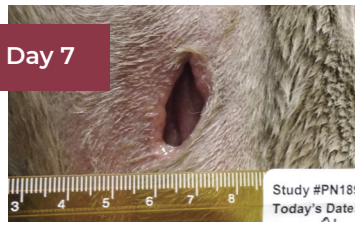
- Mild inflammation on shaved area around tumor site

Day 4



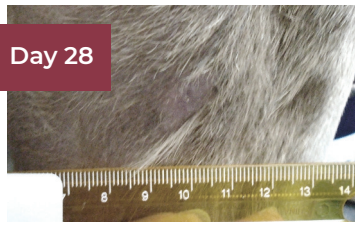
- Necrotic tumor tissue present
- In some cases, an odor may be detectable

Day 7



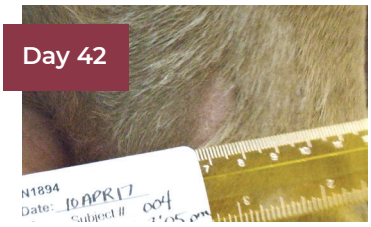
- Non-pitting edema around wound
- Drainage/exudate

Day 28



- Complete response, full wound resolution

Day 42



- Minimal scar formation

Learn more while earning CE credits. View the e-learning modules by using the camera on your smartphone to capture the QR code, or by visiting https://vet-us.virbac.com/stelfonta.

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

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References: 1. Melo S, Januário E, Pinto AC. Intra-tumoral injection of tigilanol tiglate in canine mast cell tumors: time-assessed thermographic images, computed tomography and clinical response. Proceedings of the Veterinary Cancer Society Conference 2019; October 17–19, 2019; Houston, TX. **2.** STELFONTA® (tigilanol tiglate injection) [product label]. Fort Worth, TX: Virbac AH, Inc.; 2020. **3.** Reddell P, DeRidder 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;35:430–441. **4.** DeRidder TR, Campbell JE, Burke-Schwarz C, et al. Randomized controlled clinical study evaluating the efficacy and safety of intratumoral treatment of canine mast cell tumors with tigilanol tiglate (EBC-46). *J Vet Intern Med.* 2021;35:415–429. **5.** Jones PD, Campbell JE, Brown G, Johannes CM, Reddell P. Recurrence-free interval 12 months after local treatment of mast cell tumors in dogs using intratumoral injection of tigilanol tiglate. *J Vet Intern Med.* 2020;1–5.

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