

Practical aspects of STELFONTA® (tigilanol tiglate injection): A Brief Overview



Considerations for case selection:

Tumor location, volume and ulceration along with patient stage of disease; patient concurrent medications, concurrent disease and temperament; owner ability to administer concomitant medications and comfort with wound management.

Pet Owner Education:

Refer clients to STELFONTA.com for product information. Ensure pet owners are prepared for the stages of STELFONTA® treatment including anticipating the wound, potential reactions and that they know when, with whom and how to communicate any concerns.

STELFONTA is often administered earlier in the week, so the pet owner has access to the primary treating clinician during regular working hours, to address any concerns post treatment.

Treatment protocol consists of 4 stages:

1 Concomitant medications

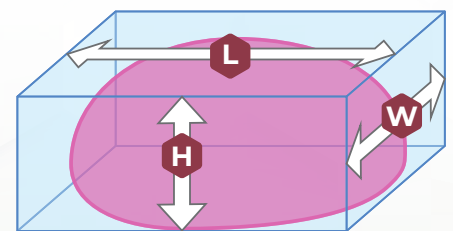
- » Reduce the risk of mast cell degranulation (including death) with **mandatory** concomitant medications:
 - Corticosteroids, commencing 2 days prior to the injection.
 - H1 and H2 Blockers, commencing on injection day, continuing for 8 days.
- » Discretionary pre-emptive pain relief to minimize discomfort during and post injection.
- » Consider administering analgesic medications prior to, during, and after treatment with STELFONTA

Drug	Day -2		Day -1		Treatment Day 0		Day 1		Day 2		Day 3		Day 4		Day 5		Day 6		Day 7		
	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	
Corticosteroid (e.g. prednisone/ prednisolone 0.5mg/kg PO)	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●			●		●	
H1 blocker (e.g. diphenhydramine 2mg/kg PO q12hr)					●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
H2 blocker (e.g. famotidine 0.5mg/kg PO q12hr)					●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●

2 STELFONTA injection

- » Sedation of patient may be required to ensure accurate and safe injection of tumor site while minimizing risk of self-injection.
- » Shave the hair surrounding the tumor.
- » Tumor surface should be intact; the drug can leak from ulcerated surfaces or biopsy sites.
- » Re-measure the tumor on the day of treatment ($L \times W \times H \times \frac{1}{2}$) and confirm the volume does not exceed 10cm³.
- » Calculate the dose: tumor volume x $\frac{1}{2}$; ensuring total dose is not more than 5mL or 0.25mL/kg.

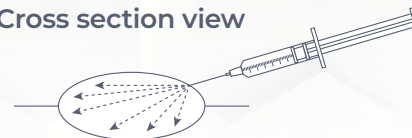
Modified ellipsoid calculation



$$L \times W \times H \times \frac{1}{2}$$

- » Administer STELFONTA® (tigilanol tiglate injection) in a fanning motion through a single injection point with a Luer-Lock syringe and 23 gauge needle.
- » Discourage the dog from licking in the first few days.
- » Plan for and provide pain relief when necessary and adjust as needed.
- » If degranulation occurs, signs are typically seen in the first 5-7 days of treatment.

Cross section view

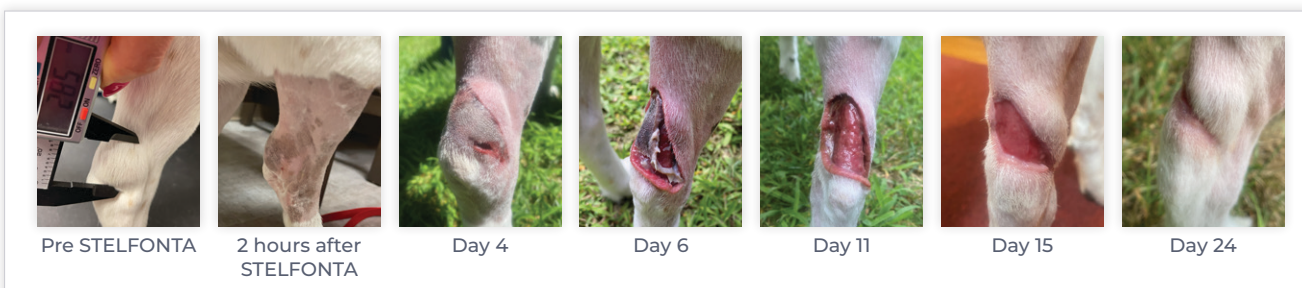


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Tumor destruction

- » Within minutes STELFONTA starts to work; within hours acute inflammatory response is evident.
- » 4 to 7 days: tumor destruction, via hemorrhagic necrosis and oncolysis, is typically seen.
- » Treated sites are usually left uncovered.
- » Necrotic tumor mass will slough away leaving a 'pocket' or wound which may be extensive.

Tumor destruction and healing typically between 4-6 weeks*



*Some cases have more extreme wounds and take longer to heal

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Tumor site healing, via second intention

- » 4-6 weeks: Wound formation is an intended and expected sign of STELFONTA® efficacy. Wound may be extensive, requiring additional management and time to heal.
 - » Tumor size determines the size of the wound, which influences the healing time, along with tumor location; typically, tumors on limbs take longer to heal.
- Non-responsive tumors may be retreated after day 28. 75% of MCTs achieve a Complete Response after one treatment, 87% after one or two treatments. If a second treatment with STELFONTA is necessary, concomitant medications should be started with the same mandatory dosing schedule.
 - STELFONTA's Mechanism of Action: three inter-related effects, specifically, oncolysis, stimulation of acute inflammatory response and increased permeability of tumor vasculature.

IMPORTANT SAFETY INFORMATION. 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. In dogs, do not inject STELFONTA into subcutaneous mast cell tumors located above the elbow or hock. Formation of wounds, possibly extensive, is an intended and likely response to treatment with STELFONTA along with associated swelling, bruising and pain; these wounds are expected to heal. Appropriate pre- and post-treatment medications must be given, including a corticosteroid plus blocking agents for both H1 and H2 receptors, in order to decrease the potential for severe systemic adverse reactions, including death, from mast cell degranulation. For full prescribing information, contact VIRBAC at 1-800-338-3659 or visit <https://vet-us.virbac.com/stelfonta>



Prescribing
information



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