

Client Information Sheet



STELFONTA[®]

(tigilanol tiglate injection)
1 mg/mL

The Client Information Sheet contains important information about STELFONTA[®]. You should read this information before your dog is treated with STELFONTA. This sheet is provided only as a summary and does not take the place of instructions from your veterinarian. Talk with your veterinarian if you do not understand any of this information or if you want to know more about STELFONTA.

Your veterinarian has decided to include STELFONTA as a part of your dog's treatment plan for a mast cell tumor. Be sure to speak with your veterinarian about all parts of your dog's treatment plan.

What is STELFONTA?

- STELFONTA is a drug used to treat mast cell tumors, a common form of skin cancer that affects dogs.
- The active ingredient in STELFONTA is tigilanol tiglate, a substance that works by:
 - Breaking down the tumor cell walls
 - Disrupting blood vessels in the tumor
 - Destroying the tumor forming a "pocket" or wound where the tumor was

What should I tell my veterinarian before my dog is treated with STELFONTA?

- Tell your veterinarian about all other medications your dog is taking, including prescription drugs, over the counter drugs, flea and tick medications, heartworm and deworming medications, and vitamins and supplements (including herbal or homeopathic products).
- Tell your veterinarian about your dog's previous or current medical conditions, including any infection.
- Tell your veterinarian if your dog is pregnant, is nursing puppies, or is intended for breeding purposes.

How is STELFONTA given to my dog?

- Your veterinarian will inject your dog's tumor with STELFONTA. The injection will be given at the veterinary clinic. Your dog may need to be sedated during the procedure.

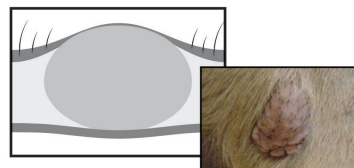
How will STELFONTA affect my dog?

- STELFONTA is used to treat a mast cell tumor on your dog. It can be difficult to predict how your dog's tumor will respond to STELFONTA.
- A wound will form where STELFONTA was administered. It is difficult to predict the size and severity of the wound formed. See the diagrams below for more information.

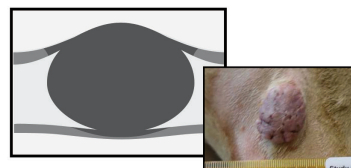
What is the treatment and healing process?

- Tumors treated with STELFONTA typically go through a 4- to 6-week treatment and healing process, as shown in the following diagrams. The healing process may take longer in some dogs.
- During the treatment and healing process, your dog may require additional care of the treated tumor site to aid in the healing process.

DAY 1: PRE-TREATMENT



2-4 HRS POST-TREATMENT

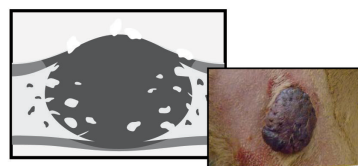


LESS THAN 4 HOURS AFTER TREATMENT:

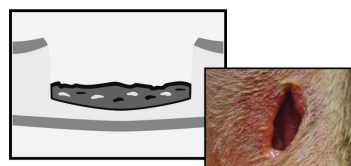
Start of Tumor Breakdown

Within the first few hours following treatment with STELFONTA, the cells in the tumor and tumor blood vessels will begin to break down. You will be able to see a change in the color of the tumor. At the same time there is usually swelling at the treated tumor site.

24 HRS POST-TREATMENT:
TUMOR BREAKDOWN EVIDENT



DAY 7: TUMOR BREAKDOWN
WITH FORMATION OF HEALTHY WOUND BED

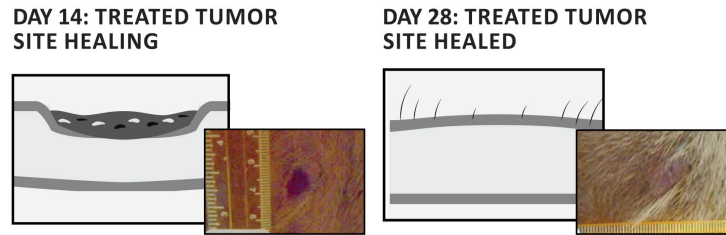


1 – 7 DAYS AFTER TREATMENT:

Continued Tumor Breakdown

The treated tumor site will become blackened. The skin over the surface of the tumor may breakdown and fluid may leak from the tumor. Swelling of the treated tumor site may continue causing some discomfort to your dog through this stage. Your veterinarian can prescribe pain medication to help your dog through this period if needed. As the tumor breaks down there will be a 'pocket' or wound where the tumor once was. A healthy wound bed will be seen, reddish in color, which will allow healthy new skin to grow.

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7 – 42 DAYS AFTER TREATMENT:

Wound Resolution

Healthy new skin will grow and close over the pocket or wound where the tumor once was. In many dogs, the hair will regrow and skin will return to its original color.

What are some possible side effects of STELFONTA® (tigilanol tiglate injection)?

- STELFONTA may cause side effects, even at the prescribed dose. These side effects include, but are not limited to:
 - During the first days after treatment, you may see bruising or swelling around the treated tumor site. The swelling may cause your dog some discomfort and pain for several days after treatment. Your dog may seem tired during this time and may eat less.
 - In some cases, a severe, larger than normal wound may develop, delaying wound healing. Your veterinarian will assess if your dog requires additional treatments during this time (e.g. bandages, Elizabethan collar).
- Other side effects may occur. For more information about side effects ask your veterinarian.

Contact your veterinarian if you notice any of the following changes in your dog:

- Excessive pain or lameness (limping)
- Tiredness or refusal to eat for more than 1 day
- Repeated vomiting or diarrhea
- Trouble breathing
- Changes to the treated tumor site, including increased or excessive swelling and bruising, extensive wound formation, or increased irritation
- Any other symptoms that your dog may show that concern you.

What do I need to know to safely care for my dog before and after treatment with STELFONTA?

- Your veterinarian will prescribe medications to decrease the potential for severe reactions that can occur during the treatment process. **It is essential that you give the medications as prescribed.**
- The treated tumor site is typically left uncovered. In some cases, your veterinarian may decide to cover the treated tumor site with a bandage.
- Some discharge from the treated tumor site following treatment is expected. The treated tumor site can be cleaned with warm water as necessary. Wear disposable gloves when cleaning the treated tumor site.
- If your dog is licking or rubbing the treated tumor site, contact your veterinarian. Your veterinarian may recommend an Elizabethan collar (“e-collar”) or a bandage to cover the wound.
- If another animal in the household is licking or grooming the treated tumor site, the animals should be separated to prevent trauma to the area.

What precautions do I need to take when caring for my dog before and after treatment with STELFONTA?

- Thoroughly wash any skin that comes in contact with the treated tumor site, wound, wound discharge, or material contaminated with wound discharge (e.g. bedding).
- Do not wash any items soiled with wound discharge with other laundry.

Is there more information?

- This client information sheet gives the most important information about STELFONTA. For more information about STELFONTA, please talk with your veterinarian.

To report a suspected adverse reaction (side effect) call 1-800-338-3659. For additional information about adverse drug experience reporting for animal drugs, contact the FDA at 1-888-FDA-VETS or online at <http://www.fda.gov/reportanimalae>.

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