

# CLIENT INFORMATION SHEET



This Client Information Sheet contains important information about STELFONTA®. Before your dog is treated, you should carefully read this information and discuss the following with your veterinarian:

- How STELFONTA works.
- All parts of your dog's treatment plan. **It is very important to follow the treatment plan exactly as directed.**
- The risks and benefits of STELFONTA, including the potential for serious side effects.

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.

## What is STELFONTA?

- STELFONTA is a drug used to treat mast cell tumors, a common form of 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 and 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.

## What additional medications need to be given to my dog before, on, and after the day of treatment with STELFONTA?

- To help prevent the potential for severe side effects that can occur, your veterinarian will prescribe three medications:
  - » You must start to give your dog the corticosteroid two days before the STELFONTA treatment day and continue for a total of 10 days.
  - » You will start giving your dog the H1 and H2 blockers on the STELFONTA treatment day and continue for a total of 8 days.

- Your veterinarian will fill out the medication schedule included in this Client Information Sheet for you to follow, so that you can give your dog the medications correctly.
- If you are unable to give your dog the medications as directed, talk to your veterinarian about other options. **Do not skip these medications.**

## 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. In some cases, an extensive wound that is deeper and/or larger than the original treatment site may develop, which may lead to unexpected complications.
- Tumors treated with STELFONTA typically go through a 4- to 6-week tumor breakdown and healing process.
- The healing process may take longer in some dogs.
- During the tumor breakdown and healing process, your dog may require additional care of the treated tumor site to aid in the healing process.

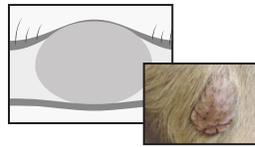
See the diagrams for more information.

## LESS THAN 4 HOURS AFTER STELFONTA TREATMENT:

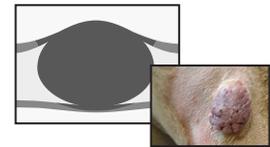
### Start of Tumor Breakdown

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.

DAY 1: BEFORE STELFONTA TREATMENT



2-4 HRS AFTER STELFONTA TREATMENT

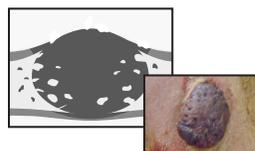


## 1-7 DAYS AFTER STELFONTA TREATMENT:

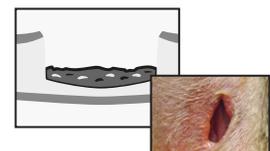
### Continued Tumor Breakdown

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.

24 HRS POST-TREATMENT: TUMOR BREAKDOWN EVIDENT



DAY 7: TUMOR BREAKDOWN WITH FORMATION OF HEALTHY WOUND BED



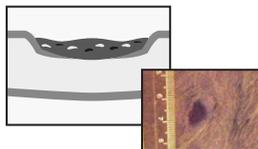
## 7 - 42 DAYS AFTER STELFONTA® (tigilanol tiglate injection)

### TREATMENT:

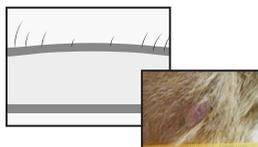
#### Wound Resolution

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.

#### DAY 14 AFTER STELFONTA TREATMENT: TUMOR SITE



#### DAY 28 AFTER STELFONTA TREATMENT: TREATED TUMOR SITE HEALED



Some dogs experience extensive wounds after STELFONTA treatment that take longer to heal, as in the case below.

Treatment day



Mast cell tumor above left paw.

24 hours post-treatment



Forelimb is swollen and painful.

7 days post-treatment



Extensive wound developed, requiring veterinary care and bandaging days 8-12.

14 days post-treatment



Wound healing; swelling and lameness present.

28 days post-treatment



Surgery needed to improve movement of leg. Splint applied for one month. No tumor present.

42 days post-treatment



Wound continues to heal; swelling and lameness present.

84 days post-treatment



Healing and limb use continues to improve. No evidence of tumor detected.

### What are some possible side effects of STELFONTA?

- 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, extensive swelling, severe pain, large amounts of discharge, odor, infection, or wound formation extending into the area surrounding the tumor site may develop, delaying wound healing and requiring additional management of the wound. If any of these occur, contact your veterinarian who will assess if your dog requires additional treatments during this time (e.g., pain medications, bandages, an Elizabethan collar, antibiotics).
  - » Amputation has been reported as a result of extensive swelling and wound formation.
  - » Mast cell degranulation can occur, especially during the first 5-7 days after treatment. Mast cell degranulation is a type of allergic reaction that occurs when inflammatory substances are released from your dog's tumor when mast cells are destroyed.

Mast cell degranulation can cause severe side effects and potentially be fatal. Contact your veterinarian if you notice any of the following signs:

- trouble breathing or excessive panting
  - excessive bruising and swelling
  - vomiting
  - diarrhea
  - hives
  - decreased appetite (refusal to eat for more than 1 day).
- Other side effects may occur. For more information about side effects ask your veterinarian.
  - Side effects can occur with or without warning, and in some cases may result in death.

**Contact your veterinarian if you notice any of the following changes in your dog. These changes may mean your dog is experiencing a serious side effect.**

- Excessive pain or lameness (limping)
- Excessive licking of the treatment site
- Tiredness, weakness or refusal to eat for more than 1 day
- Repeated vomiting or diarrhea
- Trouble breathing or excessive panting
- A rash or hives anywhere on the body
- Changes to the treated tumor site, including increased or excessive swelling and bruising, large amounts of discharge, strong odor, or extensive wound formation
- 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 allergic reactions due to mast cell degranulation that can occur during the treatment process. **It is essential that you give the medications as prescribed** (use the Medication Schedule provided below to help you keep track of the dosing schedule).
- The treated tumor site is typically left uncovered. In some cases, your veterinarian may decide to cover the treated tumor site with a bandage.
- Notify your veterinarian if your dog seems uncomfortable. Your veterinarian may prescribe additional medications for pain.
- 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.
- Do not allow your dog to lick the tumor site for the first few days after treatment. Discourage excessive licking for the remainder of the healing period.
- 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® (tigilanol tiglate injection). 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 [www.fda.gov/reportanimalae](http://www.fda.gov/reportanimalae).

**Use the Medication Schedule below to help you keep track of the medicine you need to give your dog.**

**Medication schedule**

The following medications are to be given when your pet is treated with STELFONTA to help decrease and/or prevent side effects:

- Corticosteroid (prednisone or prednisolone): Start medication as directed **two days before STELFONTA treatment day**, continue on the treatment day, and for an additional 7 days after the treatment day, which will be a total of 10 days.
  - H1 and H2 blockers (diphenhydramine and famotidine): Start medications as directed **on STELFONTA treatment day** and continue for an additional 7 days, which will be a total of 8 days.
  - Use the following chart to help you keep track of the dosing schedule, make an “X” in the box when that dose of medication is given. Do not administer the medication if the box is grayed out.
  - If you are unable to give your dog the medications orally (by mouth), or your dog is vomiting or not eating, talk to your veterinarian to determine what other options may be used for administration.
- Do not skip these medications.**

Drug	Before STELFONTA Treatment				STELFONTA Treatment Day Date:	After STELFONTA Treatment														
	2 days before Date:		1 day before Date:			1 day after Date:	2 days after Date:	3 days after Date:	4 days after Date:	5 days after Date:	6 days after Date:	7 days after Date:								
	am	pm	am	pm		am	pm	am	pm	am	pm	am	pm	am	pm	am	pm			
Corticosteroids Name:																				
H1 blocker Name:																				
H2 blocker Name:																				

Note for veterinarian – the above chart is intended to be a visual aid for the client to administer the concomitant medications correctly. Fill in the chart with the specific dates of administration and the specific names of the medications prescribed.

Space reserved for veterinarian to provide full directions for administration of concomitant medications (name of drug, route of administration, amount, frequency, and duration)

