Sedation may be necessary to safely and accurately administer STELFONTA to the dog. Precautions during STELFONTA administration:

- Always administer a corticosteroid (e.g., prednisone or prednisolone), an H2 receptor blocking agent (e.g., famotidine), and an H2 receptor blocking agent (e.g., famotidine) when treating with STELFONTA to minimize the risk of adverse events. A corticosteroid may be administered according to this Package Insert (see Dosage and Administration).

Do not inject STELFONTA into subcutaneous mast cell tumors located adjacent to a joint (e.g., on the head, hind legs, or front legs). 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 Reactions).

- 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).

Caution: This drug is toxic if skin contact or by oral contact. Use concurrent care if necessary.

STELFONTA® (tigilanol tiglate injection) 0.5 mL

INDICATION

STELFONTA® is indicated for use in dogs for the treatment of:

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

Dosage and Administration

ALWAYS PROVIDE THE CLIENT INFORMATION SHEET TO THE DOG OWNER BEFORE DOSAGE ADMINISTRATION.

Concomitant medications

Administer the following medications to decrease the potential for severe systemic reactions in dogs:

- Corticosteroids (e.g., oral prednisone or prednisolone at anti-inflammatory dose)
- Start medication 2 days prior to STELFONTA treatment and continue for 5-7 days after STELFONTA administration. You will need to continue the corticosteroid for 7 days after STELFONTA administration.

- H2 receptor blocking agent (e.g., oral diphenhydramine)
- Start medication 2 days prior to STELFONTA administration. Thereafter continue with this medication indefinitely.

- H2 receptor blocking agent (e.g., oral famotidine)
- Start medication on the day before STELFONTA administration and continue for a total of 8 days.

Dosing Instructions

Administer STELFONTA as an intratumoral injection at a dose of 0.5 mL per cm² of tumor volume, as determined by the following calculations:

- Determine the Tumor Volume in cm³
- Calculate the Dose Volume (mL) of STELFONTA to inject

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. Avoid touching of accidental self-injection wounds; abstain from alcohol. Stop injection if the dog becomes combative or agitated.

Dog Safety:

- Always administer a corticosteroid (e.g., prednisone or prednisolone), an H2 receptor blocking agent (e.g., famotidine), and an H2 receptor blocking agent (e.g., famotidine) when treating with STELFONTA to minimize the risk of adverse events. A corticosteroid may be administered according to this Package Insert (see Dosage and Administration).

- Do not inject STELFONTA into subcutaneous mast cell tumors located adjacent to a joint (e.g., on the head, hind legs, or front legs). 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 Reactions).

- 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).

Caution: This drug is toxic if skin contact or by oral contact. Use concurrent care if necessary.

STELFONTA® (tigilanol tiglate injection) 0.5 mL

For intratumoral injection in dogs only

Antineoplastic

Single-use vial

DESCRIPTION

The active ingredient for tigilanol tiglate is a phorbol ester that acts as a protein kinase C activator and mTOR activator.

Contrast (e.g., oral prednisone or prednisolone at anti-inflammation dose): Start medication 2 days prior to STELFONTA treatment and continue for 5-7 days after STELFONTA administration. You will need to continue the corticosteroid for 7 days after STELFONTA administration.

H2 receptor blocking agent (e.g., famotidine): Start medication on the day before STELFONTA administration and continue for total of 8 days.

Adverse Reactions

The safe and effective use of STELFONTA has not been evaluated in dogs with a mast cell tumor volume >10 cm³. The safe and effective use of STELFONTA has not been evaluated for dogs with tumors that are tender or firm on palpation.

Contraindications

- Do not use STELFONTA if the dog is pregnant, nursing, or if there has been ingestion, seek the advice of a physician and show them the package insert.

- Limited data is available on the potential teratogenic effects of STELFONTA. Therefore, STELFONTA should not be administered to women who are pregnant or planning to become pregnant.

- Do not use STELFONTA if the dog has had an allergic reaction to STELFONTA or any of the excipients used to make this product.

- STELFONTA is a highly irritant, and accidental exposure to skin, eye, or by ingestion should be avoided. In case of dermal or ocular exposure, repeated wash the exposed skin or eye with water. If irritant to skin, dress the affected area, then remove contacts and contacts and rinse with water. If symptoms such as local signs of redness and swelling occur, if there has been irritation, seek the advice of a physician and show them the package insert.

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TREATMENT SITE HEALING

CARCINOSARCOMA SCABREX™ (2.5 mL/cm²) OR STELFONTA ® (0.5 mL/cm²) or less

CLIENT INFORMATION SHEET

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

• STELFONTA® may cause side effects, even at the prescribed dose. These side effects include, but are not limited to:

  - during or after treatment, you may see or smell urinary or wound around the treated tumor. The swelling can be due to the dog some discomfort and pain for several days after treatment. Your dog may seem
  - repeated vomiting or diarrhea
  - trouble breathing
  - changes to the treated tumor site, including increased or excessive swelling or bruising, extensive wound formation, or increased irritation.
  - any additional symptoms that your dog may show that concern you.

What do I need to know about caring 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 period. Ask your veterinarian for specific medications as prescribed.

  - skin that comes in contact with the treated tumor site may become irritated. The irritated skin may be cleaned with water and soap and should be allowed to dry. Any additional skin that becomes irritated should be treated with a topical anti-irritant. Any skin that may remain an Elizabethan collar (“e-collar”) or a bandage may also be subjected to irritation.

• If another animal in the household is licking or grooming the treated tumor site, the animals should be separated to decrease irritation.

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 with soap and warm water. Wash and dry the skin with soap and warm water to prevent irritation.

In a pilot study, one dog with a small (0.2 cm³) cutaneous mast cell tumor located on the side of the head reduced its size and scar tissue during follow-up. In a pilot study, one dog with a small (0.2 cm³) cutaneous mast cell tumor located on the side of the head reduced its size and scar tissue during follow-up.

Kidney tubular vacuolation was observed in 7/18 (38.9%) of treated dogs.

In a 28-day unmasked field study, 10 client-owned dogs, 6-14 years old were randomized to treatment with a

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