EMA/613364/2019
EMEA/V/C/005018

Stelfonta (*tigilanol tiglate*)

An overview of Stelfonta and why it is authorised in the EU

What is Stelfonta and what is it used for?

Stelfonta is a cancer veterinary medicine used in dogs to treat mast cell tumours that are not suitable for surgery and that have not spread to other parts of the body. These tumours are a type of cancer involving mast cells. These are immune system cells, found in many tissues, that release substances such as histamine. Stelfonta is used for mast cell tumours in the skin, or in mast cell tumours in the tissues just under the skin at or below the elbow or hock. Stelfonta contains the active substance tigilanol tiglate.

How is Stelfonta used?

Stelfonta is available as an injection and can only be obtained with a prescription. It is given by a veterinarian as a single injection into the tumour, with the dose depending on tumour size. Before being given Stelfonta, dogs should receive treatment with corticosteroids and antihistamines to reduce the risks from release of large quantities of histamine and other active substances from the tumour (mast cell degranulation). If tumour tissue remains 4 weeks after treatment and the surface of the remaining mass is intact, a second dose may be given. The size of the remaining tumour should be measured, and the new dose calculated before the second dose is given.

For more information about using Stelfonta, see the package leaflet or contact your veterinarian or pharmacist.

How does Stelfonta work?

The active substance in Stelfonta, tigilanol tiglate, stimulates the action of enzymes called protein kinase C which are involved in regulating processes that can help cells grow and survive. By activating these enzymes blood supply to cells gets interrupted, resulting in the death of the cell. By injecting Stelfonta into the tumour, cancer cells will be affected, so destroying the tumour, and leaving a wound at the injection site.

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What benefits of Stelfonta have been shown in studies?

The effectiveness of Stelfonta was investigated in a field study involving 123 dogs with a single mast cell tumour up to 10 cm^3 in size at the first treatment. The tumour was intact and new, meaning it had not come back following surgery, radiation or cancer therapy. Dogs were either treated with Stelfonta or a dummy treatment.

Four weeks after first treatment, tumours in 75% of dogs (60/80) that received Stelfonta had completely disappeared (complete response) compared to 5% of dogs that received a dummy treatment. The dogs that had not responded after 4 weeks were treated with a second dose, and around half responded. Overall 87% (68/78) of dogs had a complete response with Stelfonta. Of the treated dogs with complete response, which were available for follow up 8 and 12 weeks after the second injection, 100% (59/59) and 96% (55/57), respectively, remained disease free at the site of the treated tumour.

What are the risks associated with Stelfonta?

The most common side effects with Stelfonta (which may affect more than 1 in 10 dogs) are mild to moderate pain on injection, wound formation at the injection site with pain and lameness, as well as vomiting and increased heart rate.

Stelfonta must not be used in mast cell tumours with a broken surface to avoid medicine leakage.

The medicine must not be given into the surrounding area after surgical removal of a tumour.

For the full list of side effects and restrictions of Stelfonta, see the package leaflet.

What are the precautions for the person who gives the medicine or comes into contact with the animal?

Veterinarians should inform the pet owner about the precautions to be taken at home.

People with known hypersensitivity to tigilanol tiglate or to propylene glycol (an ingredient of Stelfonta) should avoid contact with Stelfonta. The medicine is an irritant and potentially a skin sensitiser.

Accidental self-injection and accidental exposure to skin, eye, or by ingestion should be avoided as it can cause severe inflammation. Precautions that need to be taken when handling the medicine are described in the package leaflet. In case of accidental self-injection or exposure, medical advice should be sought immediately, and the package leaflet or label shown to the doctor.

Pregnant women and breastfeeding women should take care to avoid accidental self-injection, contact with the injection site, leaking product and tumour debris.

Low levels of tigilanol tiglate residues might be present in the wound debris. In case of severe leakage of wound debris, which may occur in the first weeks following injection of Stelfonta, the wound should be covered. If, however, the wound cannot be covered in order not to interrupt the healing process, the dog must be kept away from children. Wound debris should only be handled with protective equipment (disposable gloves).

In case of any contact with wound debris, the affected area(s) on the person should be thoroughly washed. Contaminated areas or bedding should be thoroughly cleaned.

Why is Stelfonta authorised in the EU?

The European Medicines Agency decided that Stelfonta's benefits are greater than its risks and it can be authorised for use in the EU.

Other information about Stelfonta

Stelfonta received a marketing authorisation valid throughout the EU on 15 January 2020.

Further information on Stelfonta can be found on the Agency's website: ema.europa.eu/medicines/veterinary/EPAR/stelfonta.

This overview was last updated in November 2019.