

MERCK ANIMAL HEALTH

Intervet Canada Corp.

16750 ROUTE TRANSCANADIENNE, KIRKLAND, QC, H9H 4M7

Order Desk: 514-428-7013

Toll-Free: 866-683-7838

Fax: Toll-free 888-498-4444; local 514-428-7014

Website: www.merck-animal-health.ca

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VITRECTO®



Merck Animal Health

Fluralaner and Moxidectin Topical Solution

Veterinary Use Only

DIN 02491729, 02491737, 02491745

DESCRIPTION:

VITRECTO (Fluralaner and Moxidectin Topical Solution) contains 280 mg/mL (28% w/v) of fluralaner and 14 mg/mL (1.4% w/v) of moxidectin. Each single use tube is formulated to provide a minimum dose of 40 mg/kg body weight of fluralaner and 2 mg/kg of moxidectin.

Non-Medicinal Ingredients: Butylhydroxytoluene, Dimethylacetamide (DMA), Glycofurool, Diethyltoluamide (DEET), Acetone.

THERAPEUTIC CLASSIFICATION:

Antiparasitic

INDICATIONS:

VITRECTO is indicated for cats and kittens 6 months of age and older and weighing 1.2 kg or greater.

VITRECTO is indicated for 2 months for:

- The treatment and prevention of flea infestations (*Ctenocephalides felis*)
- The treatment and control of tick infestations with *Ixodes scapularis* (black-legged tick)
- The prevention of heartworm disease caused by *Dirofilaria immitis*

VITRECTO is also indicated for the treatment of infections with intestinal roundworm (*Toxocara cati*; 4th stage larvae, immature adults and adults) and hookworm (*Ancylostoma tubaeforme*; 4th stage larvae, immature adults and adults).

DOSAGE AND ADMINISTRATION:

VITRECTO should be administered topically as a single dose every 2 months according to the **Dosage Schedule** below to provide a minimum dose of 40 mg fluralaner and 2 mg moxidectin per kg body weight. It is important to exactly follow a bi-monthly administration to ensure optimum prevention of heartworm disease in cats.

For prevention of heartworm disease, VITRECTO administration should begin one month after the first expected exposure to mosquitoes and continue at 2-month intervals until last exposure to mosquitoes.

If a dose is missed and a 2-month interval between doses is exceeded, administer VITRECTO immediately and resume the dosing every 2 months to minimize the opportunity for the development of adult heartworms.

When VITRECTO replaces a monthly heartworm preventative product, the first dose should be given within one month of the last dose of the former medication.

Dosage Schedule

Body Weight Ranges (kg)	Fluralaner content (mg/tube)	Moxidectin content (mg/tube)	Tubes administered	Package Colour
1.2 - 2.8	112.5	5.6	One	Lime
> 2.8 - 6.25	250	12.5	One	Dark blue
> 6.25 - 12.5*	500	25	One	Violet

* Cats over 12.5 kg should be administered the appropriate combination of tubes.

Step 1: Immediately before use, open the pouch and remove the tube.

Put on gloves provided at the point of sale.

Hold the tube at the crimped end with the cap in an upright position (tip up). The cap should be rotated clockwise or counter clockwise one full turn.

DO NOT REMOVE THE CAP. The cap is designed to stay on the tube for dosing.

The tube is open and ready for application when a breaking of the seal is felt.

Step 2: The cat should be standing or lying with its back horizontal during application. Part the fur at the administration site. Place the tube tip vertically against the skin at the base of the skull of the cat.

Step 3: Squeeze the tube and gently apply the entire contents of VITRECTO directly to the skin at the base of the skull of the cat. Avoid applying an excessive amount of solution that could cause some of the solution to run and drip off of the animal. If a second spot is needed to avoid run off, then apply the second spot slightly below the first spot.



Treatment with VITRECTO may begin at any time of the year and can continue without interruption. Due to climate variations across the country, Canada has highly variable distributions and abundance of fleas, ticks, heartworm and intestinal parasite infestations. A comprehensive plan, based on regional risk assessment, is recommended to determine an appropriate treatment schedule.

CONTRAINDICATIONS:

This product should not be given to cats with known or suspected allergy or intolerance to fluralaner, moxidectin or the non-medicinal ingredients of this product (see **DESCRIPTION** for non-medicinal ingredients).

CAUTIONS:

Avoid ingestion (see **ANIMAL SAFETY**).

Fluralaner is a member of the isoxazoline class. This class has been associated with neurological adverse reactions including tremors, ataxia, and seizures. Neurological adverse reactions have been reported in cats receiving isoxazoline class drugs, even in cats without a history of neurological disorders. Use with

caution in cats with a history of neurological disorders.

The safety of VITRECTO has not been established in breeding, pregnant and lactating cats.

WARNINGS:

- Keep out of the reach of children.
- **Do not contact or allow children to contact the application site until it is no longer noticeable on the animal's skin/fur. This includes cuddling and sharing a bed with the animal. It takes up to 48 hours for the application site to become dry, but it will be noticeable for longer.**
- This product is sticky. It binds to skin and may also bind to surfaces after spillage of the product.
- **Special precautions should be taken by the person who administers this product.**
- Adverse reactions have been reported in a small number of people after skin contact. In order to avoid contact with skin, **disposable protective gloves provided with this product at the point of sale must be worn when handling and administering the product.** If accidental skin contact occurs, wash the skin thoroughly with soap and water immediately. In some cases, soap and water are not sufficient to remove the product, therefore gloves must be worn. Wash hands after use of the product.
- This product can be harmful if ingested. If accidental ingestion occurs, seek medical advice. In order to prevent children from getting direct access to the product, keep tube(s) in unopened pouch until use. Keep unopened pouches in the original carton between uses. Dispose of used tubes immediately after use.
- Do not eat, drink or smoke while handling the product.
- This product can cause eye irritation. If accidental contact occurs, flush eyes thoroughly with water.
- **Hypersensitivity reactions to the product have been reported in a small number of people. The product should not be used by persons with a hypersensitivity to any of the active substances or the non-medicinal ingredients** (see **DESCRIPTION** for active substances and list of non-medicinal ingredients).
- The product is highly flammable. Keep away from heat, sparks, open flame or other sources of ignition.

ADVERSE REACTIONS:

Although all adverse reactions are not reported, the following information is based on voluntary post-approval drug experience reporting. It is generally recognized that this results in significant under-reporting. The adverse events listed here reflect reporting and not necessarily causality.

The following adverse events have been reported rarely¹ (reported in at least 1 but not more than 10 animals in 10,000 animals exposed) and very rarely² (reported in less than 1 in 10,000 animals exposed) and are listed by body system, in decreasing order of frequency:

Application site disorders: application site hair change¹, application site pruritus², application site erythema²

Systemic disorders: lethargy², anorexia²

Digestive tract disorders: hypersalivation², vomiting²

Neurological disorders: ataxia²

In a well-controlled, randomized U.S. field study, which included a total of 87 households and 176 treated cats (135 with VITRECTO and 41 with a topical active control), there were no serious treatment related adverse reactions. Over the 120-day study period, all potential adverse reactions were recorded; however, the adverse reactions listed reflect reporting and not necessarily causality. Reactions reported in the VITRECTO and in the active control groups included those presented in the following table:

Adverse Reaction (AR)	VITRECTO (n=135 cats)			Active control (n=41 cats)		
	Number of Cats	Number of Reports	Percentage of Cats with AR reported during the 120-Day study	Number of Cats	Number of Reports	Percentage of Cats with AR reported during the 120-Day study
Application Site Change (e.g. greasy, sticky or wet hair)	16	28	11.9%	2	4	4.9%
Vomiting	8	13	5.9%	5	20	12.2%
Alopecia	7	8	5.2%	1	1	2.4%
Pruritus	6	7	4.4%	5	5	12.2%
Application Site Pruritus	6	10	4.4%	2	2	4.9%
Diarrhea	5	5	3.7%	3	6	7.3%
Lethargy	5	5	3.7%	4	7	9.8%
Skin Textural Change (e.g. dry skin)	4	4	3.0%	0	0	0.0%
Hypersalivation	2	2	1.5%	2	2	4.9%

CLINICAL PHARMACOLOGY:

Following topical administration of VITRECTO in cats, peak fluralaner concentrations are achieved between 3 and 21 days and the elimination half-life ranges between 11 and 18 days. Peak moxidectin concentrations are achieved between 1 and 5 days and the elimination half-life ranges between 20 and 30 days.

MODE OF ACTION:

Fluralaner has a systemic mode of action and belongs to the class of isoxazoline-substituted benzamide derivatives. Fluralaner is an inhibitor of the arthropod nervous system. The mode of action of fluralaner is the antagonism of the ligand-gated chloride channels (gamma-aminobutyric acid (GABA)-receptor and glutamate-receptor).

Moxidectin has a systemic mode of action; it is a semisynthetic derivative of nemadectin, belonging to the milbemycin group of macrocyclic lactones. It binds with high affinity to glutamate-gated chloride channels of the nerves and muscles of the parasite resulting in hyperpolarization, paralysis and death.

EFFICACY:

In a well-controlled laboratory study, VITRECTO killed 100% of fleas within 12 hours after treatment and killed $\geq 92.1\%$ within 12 hours after infestation for 2 months. In another well-controlled laboratory study, VITRECTO killed $\geq 99.8\%$ of fleas within 48 hours for 2 months.

In well-controlled laboratory studies, VITRECTO demonstrated $\geq 97.9\%$ effectiveness against *Ixodes scapularis* 48 hours post-infestation for 2 months.

In well-controlled laboratory studies, VITRECTO demonstrated 100% effectiveness in preventing heartworm infections (*Dirofilaria immitis*) for 2 months.

In well-controlled laboratory studies, VITRECTO demonstrated $\geq 94.5\%$ effectiveness against adult *Toxocara cati* and $\geq 92.6\%$ effectiveness against both 4th stage larvae and immature adults infections in cats.

In well-controlled laboratory studies, VITRECTO demonstrated $\geq 94.1\%$ effectiveness against adult *Ancylostoma tubaeforme* and 100% effectiveness against both 4th stage larvae and immature adults infections in cats.

ANIMAL SAFETY:

Treatment related effects on lipid metabolism, including reductions in blood cholesterol, triglycerides and phospholipids may occur when fluralaner is administered at a higher than recommended dose or at increased dose frequency. These effects are reversible with time and are without a known or evident clinical effect.

Margin of Safety Study: In a margin of safety study, VITRECTO was administered topically to 9- to 13-week (mean age 12 weeks) old kittens at 1X, 3X, and

5X the maximum labeled dose of 93 mg/kg fluralaner + 4.65 mg/kg moxidectin at three, 8-week intervals (10 cats per group). The cats in the control group (0X) were treated with mineral oil.

There were no clinically relevant, treatment related effects on physical examination, body weights, food consumption, clinical pathology (hematology, clinical chemistries, coagulation tests, and urinalysis), gross pathology, histopathology, or organ weights.

Single incidences of self-limiting hypersalivation were observed in cats administered VITRECTO on the day of treatment.

Oral Safety Study: In a safety study, one dose of VITRECTO was administered at 1X the maximum labeled dose of 93 mg/kg fluralaner + 4.65 mg/kg moxidectin orally to 4- to 9-month-old-kittens, weighing 1.9 to 5.2 kg. The kittens in the control group (0X) were administered saline orally. There were no clinically relevant, treatment related effects on physical examination, body weights, food consumption, or clinical pathology (hematology, clinical chemistries, coagulation tests, and urinalysis). Five of six treated kittens experienced salivation. Two treated kittens experienced vomiting, 2 hours and 8 hours respectively, following oral administration.

Study in cats infected with adult heartworms: VITRECTO was administered topically to cats infected with adult heartworms (*Dirofilaria immitis*) at 1X or 3X the maximum labeled dose of 93 mg/kg fluralaner + 4.65 mg/kg moxidectin (8 cats per group). The cats in the control group (0X) received mineral oil topically. There were no clinically relevant, treatment related effects on clinical observations, physical examinations, body weights, clinical pathology (hematology, clinical chemistry, coagulation profile), gross pathology, histopathology of gross lesions or heartworm count/vitality at necropsy. Self-limiting hypersalivation following grooming was observed in the two treated groups on the day of treatment.

Two untreated cats were found dead prior to dosing (one during the pre-Study phase and one from the 0X group on Study Day 0) and three treated cats (one in the 1X group and two in the 3X group) were euthanized due to poor clinical condition (Study Days 22, 25 and 38).

According to the American Heartworm Society, the presence of 1 or 2 adult heartworms can be life-threatening in cats.

Field Studies: In a well-controlled field study, VITRECTO was used concurrently with other medications, such as vaccines, antibiotics, anthelmintics and glucocorticoids. No adverse reactions were observed from the concurrent use of VITRECTO with other medications.

STORAGE CONDITIONS:

Do not store above 25°C. Protect from freezing. Keep tube in unopened pouch until use and discard it immediately after.

HOW SUPPLIED:

VITRECTO (Fluralaner and Moxidectin Topical Solution) is available in three (3) single use tube sizes for use in cats ranging in weight from 1.2 kg to 12.5 kg. Each tube is packaged individually in a pouch. Product may be supplied in 1 or 2 tubes per carton. Not all presentations may be marketed.

Intervet Canada Corp., subsidiary of Merck & Co., Inc., 16750, route Transcanadienne, Kirkland, QC H9H 4M7

1 866 683-7838

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