NADA 141-459, Approved by FDA



(fluralaner topical solution) for Cats

BRIEF SUMMARY (For full Prescribing Information, see package insert)

Caution:

Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian. Indications:

Bravecto kills adult fleas and is indicated for the treatment and prevention of flea infestations (*Ctenocephalides felis*) and the treatment and control of *Ixodes scapularis* (black-legged tick) infestations for 12 weeks in cats and kittens 6 months of age and older, and weighing 2.6 pounds or greater.

Bravecto is also indicated for the treatment and control of *Dermacentor variabilis* (American dog tick) infestations for 8 weeks in cats and kittens 6 months of age and older, and weighing 2.6 pounds or greater.

Contraindications:

There are no known contraindications for the use of the product.

WARNINGS

Human Warnings:

Not for human use. Keep this and all drugs out of the reach of children. **Do not contact or allow** children to contact the application site until dry. Keep the product in the original packaging until use in order to prevent children from getting direct access to the product. Do not eat, drink or smoke while handling the product. Avoid contact with skin and eyes. If contact with eyes occurs, then flush eyes slowly and gently with water. Wash hands and contacted skin thoroughly with soap and water immediately after use of the product.

The product is highly flammable. Keep away from heat, sparks, open flame or other sources of ignition. **Precautions:**

For topical use only. Avoid oral ingestion. Use with caution in cats with a history of neurologic abnormalities. Neurologic abnormalities have been reported in cats receiving Bravecto, even in cats without a history of neurologic abnormalities. Bravecto has not been shown to be effective for 12-weeks duration in kittens less than 6 months of age. Bravecto is not effective against *Dermacentor variabilis* ticks beyond 8 weeks after dosing. The safety of Bravecto has not been established in breeding, pregnant and lactating cats.

Adverse Reactions:

In a well-controlled U.S. field study, which included a total of 161 households and 311 treated cats (224 with fluralaner and 87 with a topical active control), there were no serious adverse reactions. **Percentage of Cats with Adverse Reactions (AR) in the Field Study**

Adverse Reaction (AR)	Bravecto Group: Percent of Cats with the AR During the 105-Day Study (n=224 cats)	Control Group: Percent of Cats with the AR During the 84-Day Study (n=87 cats)
Vomiting	7.6%	6.9%
Pruritus	5.4%	11.5%
Diarrhea	4.9%	1.1%
Alopecia	4.9%	4.6%
Decreased Appetite	3.6%	0.0%
Lethargy	3.1%	2.3%
Scabs/Ulcerated Lesions	2.2%	3.4%

In the field study, two cats treated with fluralaner topical solution experienced ataxia. One cat became ataxic with a right head tilt 34 days after the first dose. The cat improved within one week of starting antibiotics. The ataxia and right head tilt, along with lateral recumbency, reoccurred 82 days after administration of the first dose. The cat recovered with antibiotics and was redosed with fluralaner topical solution 92 days after administration of the first dose, with no further abnormalities during the study. A second cat became ataxic 15 days after receiving its first dose and recovered the next day. The cat was redosed with fluralaner topical solution 82 days after administration of the first dose, with no further abnormalities during the study.

In a European field study, two cats from the same household experienced tremors, lethargy, and anorexia within one day of administration. The signs resolved in both cats within 48-72 hours. In a European field study, there were three reports of facial demnatiis in humans after close contact with the application site which occurred within 4 days of application.

For technical assistance or to report a suspected adverse drug reaction, or to obtain a copy of the Safety Data Sheet (SDS), contact Merck Animal Health at 1-800-224-5318. Additional information can be found at www.bravecto.com. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or online at http://www.fda.gov/AnimalVeterinary/SafetyHealth.

How Supplied:

Bravecto is available in three strengths for use in cats (112.5, 250, and 500 mg fluralaner per tube). Each tube is packaged individually in a pouch. Product may be supplied in 1 or 2 tubes per carton. Distributed by:

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SEIZE THE MOMENT

Make today the start of a healthy, new beginning. Pick up Bravecto from your veterinarian and you'll be on your way to enjoying a flea and tick-free household with a single treatment that lasts for up to 12 weeks^{*} of protection.¹ For more information, please ask your veterinarian.

Visit **Bravecto.com** for more information and promotional offers[†]

REFERENCES

 Bravecto Topical Solution for Cats [prescribing information]. Madison, NJ: Merck Animal Health; 2016.

* Bravecto Topical Solution for Cats kills fleas, prevents flea infestations, and kills ticks (black-legged tick) for 12 weeks. Bravecto also kills American dog ticks for 8 weeks.

[†] Merck Animal Health reserves the right to amend, substitute, or withdraw offer at any time without notice. Void where prohibited.

IMPORTANT SAFETY INFORMATION

The most common adverse reactions recorded in clinical trials were vomiting, itching, diarrhea, hair loss, decreased appetite, lethargy, and scabs/ulcerated lesions. Bravecto has not been shown to be effective for 12-weeks' duration in kittens less than 6 months of age. Bravecto is not effective against American dog ticks beyond 8 weeks of dosing. For topical use only. Avoid oral ingestion. The safety of Bravecto has not been established in breeding, pregnant and lactating cats. Use with caution in cats with a history of neurologic abnormalities. Neurologic abnormalities have been reported in cats receiving Bravecto, even in cats without a history of neurologic abnormalities. For complete safety information, refer to product label.

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BECAUSE YOU SEE SOMETHING DIFFERENT EXPECT THE EXTRAORDINARY



1 DOSE. 12 EXTRAORDINARY WEEKS* OF FLEA AND TICK PROTECTION.







FAST AND PERSISTENT PROTECTION

Bravecto Topical Solution is

here to help you spend more

quality time with your cat and

tick infestation. It lasts nearly

monthly treatments and is

Cat lovers appreciate the

extraordinarily long, up to

12-week* hassle-free period

between treatments and the easy

We think you and your cat will too.

to use application of Bravecto.

against ticks on cats.1

an effective topical treatment

less effort dealing with flea and

three times longer than common

EASY TO USE

5 WAYS BRAVECTO[®] HELPS YOU AND YOUR CAT



- 2 UP TO 12 WEEKS* OF PROTECTION¹ WITH JUST ONE DOSE
- 3 EASY-TO-USE APPLICATOR
- 4 MORE PROTECTION WITH FEWER TREATMENTS PER YEAR
- 5 PRESCRIBED BY YOUR VETERINARIAN¹

TWELVE-WEEKEXTRAORDINARILY EASYPROTECTIONTO APPLY

- EASY TOPICAL APPLICATION
 EASY-TO-USE NON-SPILL TWIST APPLICATOR
 - LESS TREATMENTS PER YEAR

With Bravecto's unique topical solution, you and your cat can enjoy up to 12 weeks* of protection¹ with this easy-to-use treatment.

The friendly Twist'n'Use™ system removes any worries about the cap. It doesn't come off – just twist the cap to break the seal and apply. No fears about the cat swallowing the cap – complete peace of mind.

A single dose protects and remains working for almost three times longer than monthly treatments.¹ Apply Bravecto with the convenience and confidence of knowing your cat is protected for up to 12 weeks.*¹

ENJOY MORE OF THE MOMENTS THAT MATTER

MORE TREATS, LESS TREATMENT

Get back to enjoying more cuddles and comfort time with your adorable cat. With Bravecto, your cat will be protected for up to 12 weeks* with a single dose¹ – freeing you up to spend positive quality time with your cat instead.

NO MORE WORRIES ABOUT:

- WAITING FOR PROTECTION TO BEGIN
- SCHEDULING MONTHLY TREATMENTS
- HOUSEHOLD FLEA INFESTATIONS
- RETURN OF FLEA INFESTATIONS

WHY BRAVECTO?

Bravecto Topical Solution is prescribed by veterinarians to cats in the fight against fleas and ticks. We've invested in rigorous clinical trials to produce a safe and effective treatment.

MAXIMUM IMPACT, ZERO COMPROMISE

- SUITABLE FOR ALL CATS 6 MONTHS OR OLDER¹
- APPROVED FOR CATS OVER 2.6 LBS.¹
- TESTED AT 5 TIMES THE MAXIMUM CLINICAL DOSE¹
- ONE TREATMENT. UP TO 12 WEEKS* OF PROTECTION¹

