Fact Sheet for Veterinarians: Emergency Use Authorization of Bravecto (fluralaner) Chews for New World Screwworm (NWS)

Bravecto (fluralaner) chews are an oral ectoparasiticide for use in dogs and puppies. The recommended minimum dose is 11.4 mg/lb (25 mg/kg) fluralaner. Bravecto is available in five flavored chewable tablet sizes.

Original EUA Authorized Date: 11/3/2026

Emergency Use Authorization of Bravecto (fluralaner) chews for NWS

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for the emergency use of the approved product Bravecto (fluralaner) chews for the treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax)* larvae (myiasis) in dogs and puppies. Bravecto is not approved for this use.

Bravecto (fluralaner) (NADA 141-426) is approved for other uses in dogs and puppies 6 months of age and older, and weighing 4.4 pounds or greater.[1]

Limitations of Authorized Use

Bravecto (fluralaner) chews are authorized for this use only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of Bravecto (fluralaner) under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or the authorization is revoked sooner.

Justification for Emergency Use of Animal Drugs for NWS

The Secretary of the U.S. Department of Health and Human Services (HHS) has:

- determined that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves NWS (*Cochliomyia hominivorax*); and

- declared that circumstances exist justifying the authorization of emergency use of animal drugs to treat or prevent NWS myiasis in animals.[2]

An EUA is an FDA authorization for the emergency use of an unapproved product or unapproved use of an approved product (i.e., drug, biological product, or device) in the United States under certain circumstances declared by the Secretary of HHS to justify emergency use

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[1] Bravecto kills adult fleas and is approved for the treatment and prevention of flea infestations (*Ctenocephalides felis*), and the treatment and control of tick infestations [*Ixodes scapularis* (black-legged tick), *Dermacentor variabilis* (American dog tick), *Rhipicephalus sanguineus* (brown dog tick), and *Haemaphysalis longicornis* (Asian longhorned tick)] for 12 weeks in dogs and puppies 6 months of age and older, and weighing 4.4 pounds or greater. Bravecto is also indicated for the treatment and control of *Amblyomma americanum* (lone star tick) infestations for 8 weeks in dogs and puppies 6 months of age and older, and weighing 4.4 pounds or greater.

[2] See U.S. Department of Health and Human Services, Declaration of Emergency Pursuant to the Federal Food, Drug, and Cosmetic Act for New World Screwworm, August 20, 2025: https://www.federalregister.gov/documents/2025/08/20/2025-15918/declaration-of-emergency-pursuant-to-the-federal-food-drug-and-cosmetic-act-for-new-world-screwworm

authorization, including, among others, a determination that there is a public health emergency or a significant potential for a public health emergency that may affect national security and that involves a biological agent.[3]

Criteria for issuing an EUA include:

- The biological agent(s) can cause a serious or life-threatening disease or condition;
- Based on the totality of available scientific evidence (including data from adequate and well-controlled clinical trials, if available), it is reasonable to believe that:
    - the product may be effective in diagnosing, preventing, or treating the serious or life-threatening disease or condition; and
    - the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product; and
- There is no adequate, approved,[4] and available alternative to the product for diagnosing, preventing, or treating the serious or life-threatening disease or condition.[5]

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Product Description

Refer to the Bravecto package insert for full **Product Description** information.

Dosage and Administration

Bravecto should be administered orally as a single dose according to the **Dosage Schedule** below to provide a minimum dose of 11.4 mg/lb (25 mg/kg) body weight.

Bravecto should be administered with food.

Dosage Schedule

Body Weight Ranges (lb)	Fluralaner Content (mg)	Chews Administered
4.4 – 9.9	112.5	One
>9.9 – 22.0	250	One
>22.0 – 44.0	500	One
>44.0 – 88.0	1000	One
>88.0 – 123.0*	1400	One

*****Dogs over 123.0 lb should be administered the appropriate combination of chews.

[3] Emergency Use Authorization of Medical Products and Related Authorities | FDA (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities)
[4] "Approved" products include conditionally approved products for purposes of EUAs issued under Section 564 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3.
[5] https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

Risk-Benefit Consideration for Dogs on Other Isoxazoline Products:

The isoxazoline drug class carries a known risk of neurologic adverse reactions, including tremors, ataxia, and seizures, that have been reported even in dogs with no prior seizure history. If a dog is currently receiving another isoxazoline product for routine ectoparasite control, veterinarians should consider administering Bravecto to dogs diagnosed with NWS larvae based on a risk-benefit assessment and the emergency nature of the treatment of NWS infestation.

Additionally, quantifiable fluralaner concentrations were measured through 112 days after oral administration (refer to the **Clinical Pharmacology** section of the package insert). Veterinarians should consider the impact of administering Bravecto for the treatment of NWS myiasis on subsequent routine isoxazoline administration for at least three months. Administration of an isoxazoline product while there are still quantifiable fluralaner blood levels may increase the risk of isoxazoline adverse reactions.

Information Supporting Emergency Use Authorization

Based on the totality of scientific evidence available to FDA, including data from a field effectiveness study, it is reasonable to believe that Bravecto (fluralaner) chews may be effective for the treatment of NWS myiasis in dogs and puppies, and when used under the conditions described in this authorization, the known and potential benefits of Bravecto (fluralaner) hews outweigh the known and potential risks.

Title**:** Evaluation of the Therapeutic Efficacy of Bravecto Chewable Tablet against New World Screwworm (*Cochliomyia hominivorax*) Infestation in Dogs. (Study No. S25220-00)

Study Design: The study was conducted at three sites in Brazil in 2026. Fifteen mixed-breed and purebred client-owned dogs (purebred dogs included German Shepherd, Lhasa Apso, Pit Bull, and Labrador Retriever), 14 males and 1 female, between 4 months and 17 years old, weighing between 5.8 and 32.9 kg were enrolled. The dogs presented with naturally-occurring wounds that were infested with New World screwworm (*Cochliomyia hominivorax*) larvae.

The study contained one treatment group. All dogs received Bravecto, orally, at the labeled dose. For inclusion, each animal was evaluated, through visual observation, for the presence of *C. hominivorax* larvae in the wounds for myiasis diagnosis. The dog had its whole body examined systematically from the head, trunk, tail, ventral abdomen, and limbs by parting the hairs, palpation, and observation for wounds with maggots. One of the larvae was collected from each dog and evaluated for identification and confirmation of the species. The number of larvae present in the wound was visually estimated before treatment and the location of the lesions were recorded.

Drug administration was on Day 0. Dogs were administered Bravecto according to the approved, labeled dose. Bravecto was offered to the dog for voluntary uptake. If the tablet was not taken up voluntarily by the dog, it could also be given with food, water, or directly into the mouth. If the dog did not consume food within 1 hour prior to the intended dosing time, the dispenser offered food to the dog.

On Day 1 (24 hours post-treatment), the wounds were evaluated for the presence of *C. hominivorax* larvae. The larvae were counted and recorded as dead or alive.

Results: All dogs entered the study with a range of estimated live larval counts between 2 and 100 and no estimated dead larvae. At 24 hours post-treatment, only dead larvae and no live larvae were collected from the wound(s) of each dog. The larvicidal effectiveness was 100%. There was no information on whether larvae were expelled and quantified.

Adverse Reactions: No adverse reactions were reported in this study.

Conclusions: The results of this study demonstrate that Bravecto may be effective for the treatment of infestations caused by New World screwworm (*C. hominivorax*) larvae (myiasis) in dogs and puppies. The limitations of this study include conduct in a limited population of 15 dogs. Additionally, the lack of a control group and information on expelled larvae confound the ability to define a pure treatment effect and primary mechanism of action (larvicidal vs. expulsion), respectively.

Warnings

Not for human use. Keep this and all drugs out of the reach of children. 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. Wash hands thoroughly with soap and water immediately after use of the product.

To obtain a Safety Data Sheet (SDS), contact Merck Animal Health at 1-800-224-5318.

Animal Safety Warnings and Precautions

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

Adverse events have been reported following use in breeding females. Before use in breeding female dogs, refer to the **Post-Approval Experience** and **Animal Safety** sections in the Bravecto package insert.

The effectiveness of Bravecto for the treatment of NWS in puppies less than 6 months of age or weighing less than 4.4 lbs has not been tested. Puppies (8- to 9-weeks old) have lower peak fluralaner concentrations (C_{max}) when compared to adult dogs, which may result in reduced effectiveness.

The effectiveness of Bravecto for the prevention of NWS for the dosing interval (8- or 12-weeks) has not been tested. Dogs may become reinfested after treatment.

A margin of safety study was conducted in 8-week-old puppies for the original approval, dated May 25, 2014. The safety of Bravecto has not been tested in puppies less than 8 weeks of age or weighing less than 4.4 lbs.

Effective treatment of NWS myiasis includes removal of the larvae. Appropriate wound care, including surgical debridement as needed and pain management, should be implemented.[6]

[6] Cutolo, A. A., Perier, N., Menz, I., Thyssen, P., Silva, F. O., & Beugnet, F. (2021). Efficacy of afoxolaner (NexGard®) on the treatment of myiasis caused by the New World screwworm fly *Cochliomyia hominivorax* (Diptera: Calliphoridae) in naturally infested dogs. *Veterinary parasitology, regional studies and reports*, *24*, 100569.

Refer to the Bravecto package insert for full **Precautions** information.

Adverse Reactions

Refer to the Bravecto package insert for full prescribing information, including **Animal Safety**, **Adverse Reactions**, and **Post-Approval Experience**.

As described in the Letter of Authorization, veterinary facilities and veterinarians must report all **SERIOUS ADVERSE EVENTS*** potentially related to Bravecto (fluralaner) use under this EUA by:

(1) contacting Merck Animal Health at 1-800-224-5318,

(2) downloading and submitting Form FDA 1932a available at https://www.fda.gov/reportanimalae, or

(3) contacting FDA at 1-888-FDA-VETS to request this form.

When reporting adverse events on Form FDA 1932a, include the following elements when applicable and/or available:

- Patient demographics (e.g., age, species and breed, sex, weight)
- The statement "Bravecto (fluralaner) use for NWS under an EUA" under the **"Adverse Event/Product Problem/Product Use Error"** heading
- Information about the serious adverse event (e.g., signs and symptoms, test/laboratory data, timing of drug administration in relation to the occurrence of the event, duration of the event, treatment required to mitigate the event, evidence of event improvement/disappearance after stopping/reducing the dosage, evidence of reappearance after reintroduction, clinical outcomes)
- Patient's pre-existing medical conditions and use of concomitant products
- Information about the product (e.g., dosage, route of administration, lot number)

*Serious adverse events are defined as:

- Death
- A life-threatening adverse event
- An event that causes an abortion, stillbirth, or infertility
- A congenital anomaly or birth defect in offspring of treated animals
- A prolonged or permanent disability (e.g., persistent or significant incapacity or disruption of normal life functions)
- An event that requires professional intervention (e.g., important medical events that may require a medical/surgical intervention to prevent a death, life-threatening event, hospitalization, disability)

Reporting of lack of effectiveness, nonserious adverse events, or product quality defects is strongly encouraged via the mechanisms and including the information identified above for **SERIOUS ADVERSE EVENTS**.

Additional Information for Veterinarians

Veterinary facilities and veterinarians will ensure that they are aware of and adhere to the terms of the Letter of Authorization. Fact Sheets will be made available to veterinarians.

Veterinary facilities and veterinarians will ensure that the client is aware that the drug is authorized for emergency use, but not approved, for the treatment of NWS myiasis and advise the client of the risks, benefits, and any alternatives.

Veterinary facilities will maintain health records that include the following information: client name, patient name, patient age, disease manifestation, number of doses prescribed or administered per patient, lot number prescribed or administered, and other drugs co-administered. The records shall be maintained in a manner that allows veterinary facilities to identify in a reasonable time which patients received drugs subject to this EUA.

Veterinary facilities will maintain any health records for the authorized use in the Letter of Authorization for at least two years following the termination of the declaration or the revocation of the authorization, or until notified by HHS, or FDA, whichever is sooner. Such records will be made available to Intervet, Inc., HHS, and FDA for inspection upon request.

Information for Client (e.g., Animal Owner)

The lifecycle for *C. hominivorax* is as short as 21 days and wounds can be rapidly infested. Proper wound care and management practices are essential for preventing NWS myiasis. Dogs may become reinfested following treatment. Clients should be advised that:

- Gloves should be worn if cleaning the wound, or the dog's bedding, or disposing of larvae.
- Dogs should be housed to prevent exposure to NWS flies until wounds have fully healed.
- Live larvae may exit the wound and be deposited on bedding or areas where the dog sits or lies after treatment.
- If expelled larvae are seen, owners should place the larvae in a sealed container with rubbing alcohol.
- If there is worsening of the wound, the owner should contact the veterinarian.

Storage Information

Refer to the Bravecto package insert for full **Storage Conditions** information.

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