

Date of Authorization: February 18, 2026

# FREEDOM OF INFORMATION (FOI) SUMMARY

Original Emergency Use Authorization (EUA)

EUA 006685

NexGard®

(afoxolaner)

Chewable Tablet

Dogs

Scope of Authorization: For the treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in dogs and puppies.

Sponsored by:

Boehringer Ingelheim Animal Health USA, Inc.

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**I. GENERAL INFORMATION**

**A. File Number**

EUA 006685

**B. Sponsor**

Boehringer Ingelheim Animal Health USA, Inc.  
3239 Satellite Blvd.  
Duluth, GA 30096

Drug Labeler Code: 000010

**C. Proprietary Name**

NexGard®

**D. Drug Product Established Name**

afoxolaner

**E. Pharmacological Category**

Antiparasitic

**F. Dosage Form**

Chewable tablet

**G. Amount of Active Ingredient**

Each chewable contains 11.3 mg, 28.3 mg, 68 mg, or 136 mg of afoxolaner.

**H. How Supplied**

NexGard® is available in four sizes of beef-flavored soft chewables: 11.3, 28.3, 68, or 136 mg afoxolaner. Each chewable size is available in color-coded packages of 1, 3, or 6 beef-flavored chewables.

**I. Dispensing Status**

Prescription (Rx)

**J. Dosage Regimen**

NexGard® is given orally at the minimum dosage of 1.14 mg/lb (2.5 mg/kg).  
NexGard® should be used in conjunction with the mechanical removal of larvae (live and dead) remaining in the wound after treatment.

**Dosing Schedule:**

<b>Body Weight</b>	<b>Afoxolaner Per Chewable (mg)</b>	<b>Chewables Administered</b>
4 to 10 lbs.	11.3	One
10.1 to 24 lbs.	28.3	One
24.1 to 60 lbs.	68	One
60.1 to 121 lbs.	136	One
Over 121 lbs.	Administer the appropriate combination of chewables	Administer the appropriate combination of chewables

**K. Route of Administration**

Oral

**L. Species**

Dogs

**M. Food and Drug Administration (FDA) Approved Indications**

NexGard<sup>®</sup> (NADA 141-406) 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), *Dermacentor variabilis* (American dog tick), *Amblyomma americanum* (lone star tick), *Rhipicephalus sanguineus* (brown dog tick), and *Haemaphysalis longicornis* (longhorned tick) infestations in dogs and puppies 8 weeks of age and older, weighing 4 pounds of body weight or greater, for one month. NexGard<sup>®</sup> is indicated for the prevention of *Borrelia burgdorferi* infections as a direct result of killing *Ixodes scapularis* vector ticks.

**N. Emergency Authorized Use**

For the treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in dogs and puppies.

**O. Limitations of Authorized Use**

NexGard<sup>®</sup> (afoxolaner) is authorized for this use only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of NexGard<sup>®</sup> (afoxolaner) 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.

**II. EFFECTIVENESS**

**A. Dosage Characterization**

This Emergency Use Authorization does not change the previously approved dose of 1.14 mg/lb (2.5 mg/kg), given orally. The FOI Summary for the original approval of

NADA 141-406, dated September 14, 2013, contains dosage characterization information for dogs.

## B. Evidence Supporting Emergency Use Authorization

In accordance with Section 564 of the FD&C Act, the sponsor demonstrated that it is reasonable to believe that NexGard® may be effective for the treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in dogs and puppies based on published scientific literature. The evidence supporting effectiveness is based on a published article in dogs naturally infested with New World screwworm (NWS) and a published article in dogs naturally infested with Old World screwworm (OWS). The data support that it is reasonable to believe that NexGard® may be effective for the treatment of infestations caused by NWS (*C. hominivorax*) larvae (myiasis) in dogs and puppies.

### 1. Published literature

- a. Cutolo, A.A., Perier, N., Menz, I., Thyssen, P., Silva, F.O., & Beugnet, F. (2021). Effectiveness 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.

The study, conducted in Brazil over a 13-month period, evaluated 14 privately owned dogs naturally infested with *C. hominivorax* larvae. After diagnosis of myiasis by observation of larvae in a wound, all dogs were administered a single dose of NexGard® (afoxolaner) orally at the recommended labelled dose for the approved indications (2.5 mg afoxolaner/kg body weight). The study did not include a control group. The number of larvae present in the wound was visually estimated before treatment and the lesion location was recorded. Dogs were kept under supervision in an enclosed area for 24 hours after treatment (e.g., kennel, room inside the dog owner's house or veterinary clinic). At 24 hours post-treatment, the lesions were evaluated, and all remaining larvae were mechanically removed from the wound. Expelled larvae were collected from the ground or around the dog. Infestations were classified based on larvae recovered as light (10 larvae), mild (10 to 20 larvae), or severe (more than 20 larvae). All larvae (expelled and mechanically removed) were dead 24 hours post-treatment. Larvicidal effectiveness was 100% at 24 hours post-treatment.

Three dogs living in the same household developed *C. hominivorax* myiasis over a 41-day period. The first dog developed myiasis and was treated with NexGard® (afoxolaner). The dog continued to live in the home environment while the wound was healing. Twenty-three days after the first dog was diagnosed and treated, the second dog was diagnosed with *C. hominivorax* myiasis, indicating active female fly activity in the environment. The second dog was treated with NexGard® (afoxolaner). Both dogs were reexamined on the same day (33 days post-treatment for the first dog, 11 days post-treatment for the second dog). Neither dog had larval infestations. Eighteen days after the second dog was treated (41 days post-treatment for the first

dog), the third dog was diagnosed with *C. hominivorax* myiasis and treated with NexGard® (afoxolaner). Three days after the third dog was treated (44 days post-treatment for the first dog, 21 days post-treatment for the second dog), all the dogs were reexamined. No dog had larval infestations.

One other dog in the study presented with an extensive wound on the back of its neck that was reported to be repeatedly infested with *C. hominivorax* larvae. Twenty-nine days after diagnosis of myiasis and treatment with NexGard® (afoxolaner), the lesion was almost completely healed, and no larval infestations were reported within that time.

No adverse events were recorded.

The study supports that NexGard® may be effective for the treatment of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis). More information is needed to evaluate the use of NexGard® for the prevention of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis).

- b. Han, H.S., Chen, C., Schievano, C. and Noli, C. (2018). The comparative efficacy of afoxolaner, spinosad, milbemycin, spinosad plus milbemycin, and nitenpyram for the treatment of canine cutaneous myiasis. *Veterinary dermatology*. 10.1111/vde.12548.

The study evaluated 40 privately owned dogs with naturally occurring cutaneous myiasis; 8 dogs were treated with NexGard® (afoxolaner; range 2.7 to 6.8 mg/kg). All screwworms were presumed to be *Chrysomya bezziana* (OWS), but morphological confirmation was not performed. Dogs were randomized to five treatment groups, eight dogs per group, and dosed orally at doses recommended by the manufacturer for treatment of their approved target parasite species. Dogs were evaluated hourly for 7 hours and again 24-hours post-treatment. Observations were recorded as no observed effect, partial paresis/death of some larvae and its expulsion, and complete death of all larvae. Dogs with live larvae present at 24 hours were then treated with topical organophosphates. The NexGard® treatment group had live larvae 7 hours post-treatment but achieved complete larval kill in all dogs 24-hours post-treatment. The mean speed of onset was 4 hours and the mean time for complete eradication of larvae was 12 hours.

There are limitations of the data supporting the benefits of NexGard® for treatment of infestations caused by NWS in dogs. The Cutolo et al. study was conducted in a limited population of 14 naturally infested dogs in Brazil. The lack of a control group confounds the ability to define a pure treatment effect. The Han et al. study was conducted with presumptive OWS infestations. The comparability of OWS and NWS is unknown.

### III. TARGET ANIMAL SAFETY

FDA did not require target animal safety studies for this authorization. The FOI Summary for the original approval of NADA 141-406, dated September 14, 2013, contains a summary of target animal safety studies for dogs. The safety of NexGard® has not been evaluated in dogs less than 8 weeks of age or less than 4 lbs. It is reasonable to believe that the known and potential benefits of NexGard® outweigh the known and potential risks for dogs of all ages and weights because NWS myiasis is potentially fatal in dogs if left untreated, therefore justifying including dogs less than 8 weeks of age or less than 4 lbs. in this authorization.

### IV. HUMAN FOOD SAFETY

This drug is intended for use in dogs. Because this new animal drug is not intended for use in food-producing animals, FDA did not require data pertaining to drug residues in food (i.e., human food safety) for this authorization.

### V. USER SAFETY

The product Fact Sheet contains the following information regarding safety to humans handling, administering, or exposed to NexGard®:

Not for use in humans. Keep this and all drugs out of the reach of children. In case of accidental ingestion, contact a physician immediately.

### VI. AGENCY CONCLUSIONS

Based on the totality of scientific evidence available to FDA, including data from published scientific literature, it is reasonable to believe that NexGard®, when used as authorized, may be effective for the treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in dogs and puppies. The known and potential benefits of NexGard® (i.e., treating a potentially fatal disease), when used as authorized, outweigh the known and potential risks associated with use of the drug. Furthermore, there are no approved alternatives for dogs and puppies under 8 weeks of age or weighing less than 3.3 pounds because the conditionally approved product is approved to treat NWS in dogs and puppies at least 8 weeks of age and weighing at least 3.3 pounds. Additionally, there are no adequate approved alternative products containing a single active ingredient. The conditionally approved product contains multiple active ingredients, use of which may increase the likelihood of adverse events in dogs recently treated with a heartworm preventative or other antiparasitic drug in the same class as one of the ingredients in the conditionally approved product. Therefore, NexGard® containing only a single active ingredient may minimize the potential for adverse events in these dogs.

For additional information on all products authorized or conditionally approved for use with New World screwworm, please see FDA's "New World Screwworm: Information for Veterinarians" webpage at <https://www.fda.gov/animal-veterinary/safety-health/new-world-screwworm-information-veterinarians>.

**A. Duration of authorization: Revision and Revocation**

This EUA will be effective until revoked under section 564(g) of the FD&C Act or until the Secretary's declaration of emergency or threat justifying emergency authorized use is terminated (Section 564(f)(1)), with exception for continued use permissible under Section 564(f)(2). FDA may revoke or revise this authorization if emergency use of this animal drug for NWS myiasis is no longer justified, if the product no longer meets the criteria for issuance of an EUA under section 564(c) of the FD&C Act, or other circumstances make such revision or revocation of the authorization appropriate to protect the public health or safety (section 564(g)(2) of the FD&C Act).

**B. Marketing Status**

This product is authorized to be dispensed only by or on the order of a licensed veterinarian (Rx marketing status).