Fact Sheet for Veterinarians: Emergency Use Authorization of NexGard (afoxolaner) Chewables for New World Screwworm (NWS)

NexGard
(afoxolaner)
Chewables
For oral use in dogs

Original EUA Authorized Date: 02/18/2026

Emergency Use Authorization for NexGard (afoxolaner) chewables 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 NexGard (afoxolaner) for the treatment of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) in dogs and puppies. NexGard is not approved for this use.

NexGard (afoxolaner) (NADA 141-406) is approved for other uses in dogs and puppies.[1]

Limitations of Authorized Use

NexGard (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 (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.

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 authorization, including, among others, a determination that there is a public health emergency

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[1] NexGard 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 is indicated for the prevention of *Borrelia burgdorferi* infections as a direct result of killing *Ixodes scapularis* vector ticks.

[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

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 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, and available alternative to the product for diagnosing, preventing, or treating the serious or life-threatening disease or condition.[4]

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

Product Description

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

Dosage and Administration

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 (see **Precautions**).

Dosing Schedule:

Body Weight	Afoxolaner Per Chewable (mg)	Chewables Administered
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	

NexGard can be administered with or without food.

[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] https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

If suspected that any of the dose has been lost or if vomiting occurs within two hours of administration, redose with another full dose.

NexGard is not available in scored tablets. The effectiveness of the administration of less than full tablets has not been evaluated.

Risk-Benefit Consideration for Dogs on Other Isoxazolines:
If a dog is currently receiving another isoxazoline product for routine ectoparasite control, veterinarians should consider administering NexGard to dogs diagnosed with NWS larvae based on a risk-benefit assessment and the emergency nature of the treatment of NWS infestation.

Information Supporting Emergency Use Authorization

Based on the totality of scientific evidence available to FDA, including data from published scientific literature, it is reasonable to believe that NexGard (afoxolaner) chewables may be effective for the treatment of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) in dogs and puppies, and when used under the conditions described in the authorization, the known and potential benefits of NexGard (afoxolaner) chewables outweigh the known and potential risks.

1. A study conducted in Brazil over a 13-month period by Cutolo et al.[5], 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. 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. 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 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

[5] 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.

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).

2. A study conducted by Han et al.[6] evaluated 40 privately owned dogs with naturally occurring cutaneous myiasis; 8 dogs were treated with NexGard (range 2.7 to 6.8 mg/kg). All screwworms were presumed to be *Chrysomya bezziana* (Old World screwworm (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.

The available clinical data supporting the effectiveness of NexGard against *C. hominivorax* larvae, along with the established safety profile, support the potential benefit of NexGard in the authorized patient population for treatment of infestations caused by NWS larvae.

Contraindications

There are no known contraindications for the use of NexGard.

Warnings

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.

Keep NexGard in a secure location out of reach of dogs, cats, and other animals to prevent accidental ingestion or overdose.

[6] 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.

To obtain a Safety Data Sheet(s), contact Boehringer Ingelheim Animal Health USA Inc. at 1-888-637-4251 or www.nexgardforpets.com.

Precautions

Afoxolaner 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.

The safe use of NexGard in breeding, pregnant or lactating dogs has not been evaluated.

The safety of NexGard has not been evaluated in dogs less than 8 weeks of age or less than 4 lbs body weight.

Effective treatment of NWS myiasis includes removal of the larvae. Appropriate wound care, including surgical debridement as needed and pain management, should be implemented.[7]

Adverse Reactions

Refer to the 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 NexGard (afoxolaner) chewables use under this EUA (1) by contacting Boehringer Ingelheim Animal Health USA Inc. at 1-888-637-4251, (2) by 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 “NexGard (afoxolaner) 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)

[7] Cutolo et al, Effectiveness of afoxolaner (NexGard®) on the treatment of myiasis caused by the New World screwworm fly *Cochliomyia hominivorax* (Diptera: Calliphoridae) in naturally infested dogs. Vet Parasitol Reg Stud Rep. 2021:24:100569

*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 this Letter of Authorization for at least two years following the termination of the declaration or revocation of the authorization, or until notified by HHS, or FDA, whichever is sooner. Such records will be made available to Boehringer Ingelheim Animal Health USA 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.

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.

Storage Information

Store at or below 30°C (86°F) with excursions permitted up to 40°C (104°F).

Marketed by: Boehringer Ingelheim Animal Health USA Inc. Duluth, GA 30096

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