Date of Authorization: February 18, 2026

FREEDOM OF INFORMATION (FOI) SUMMARY

Original Emergency Use Authorization (EUA)

EUA 006686

NexGard® COMBO

(esafoxolaner, eprinomectin, and praziquantel topical solution)

Cats

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

Sponsored by:

Boehringer Ingelheim Animal Health USA, Inc.

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I. GENERAL INFORMATION

A. File Number

EUA 006686

B. Sponsor

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

Drug Labeler Code: 000010

C. Proprietary Name

NexGard® COMBO

D. Drug Product Established Name

esafoxolaner, eprinomectin, and praziquantel topical solution

E. Pharmacological Category

Antiparasitic

F. Dosage Form

Topical solution

G. Amount of Active Ingredient

Esafoxolaner – 12 mg/mL
Eprinomectin – 4 mg/mL
Praziquantel – 83 mg/mL

H. How Supplied

NexGard® COMBO is packaged as a single dose in 0.3 mL (for cats 1.8 – 5.5 lb) and 0.9 mL (for cats 5.6 – 16.5 lb) applicators.

Each size applicator is available in cartons containing 1, 3 or 6 applications.

I. Dispensing Status

Prescription (Rx)

J. Dosage Regimen

NexGard® COMBO is dosed at a minimum of 0.055 mL/lb (0.12 mL/kg), which delivers a minimum dose of 0.65 mg/lb (1.44 mg/kg) esafoxolaner, 0.22 mg/lb (0.48 mg/kg) eprinomectin, and 4.53 mg/lb (9.98 mg/kg) praziquantel.

Administer the entire contents of a NexGard® COMBO unit applicator topically as specified in the table below.

NexGard® COMBO should be used in conjunction with the mechanical removal of larvae (live and dead) remaining in the wound after treatment.

Dosing Schedule:

Cat Weight (lb)	Volume (mL)	Esafoxolaner (mg)	Eprinomectin (mg)	Praziquantel (mg)
1.8 – 5.5	0.3	3.6	1.2	24.9
5.6 – 16.5	0.9	10.8	3.6	74.7
16.6 – 22	0.3 + 0.9	14.4	4.8	99.6
22.1 – 33	0.9 + 0.9	21.6	7.2	149.4

A veterinarian or veterinary technician should demonstrate or instruct the pet owner regarding the appropriate technique for applying NexGard® COMBO topically to cats and kittens prior to first use. Keep product in original packaging until ready to use.

Do not apply product directly into wound or onto larvae.

K. Route of Administration

Topical

L. Species

Cats

M. Food and Drug Administration (FDA) Approved Indications

NexGard® COMBO (NADA 141-570) is indicated for the prevention of heartworm disease caused by *Dirofilaria immitis* and for the treatment and control of roundworm (fourth stage larval and adult *Toxocara cati*), hookworm (fourth stage larval and adult *Ancylostoma tubaeforme*; adult *Ancylostoma braziliense*), and tapeworm (*Dipylidium caninum*) infections. NexGard® COMBO kills adult fleas (*Ctenocephalides felis*) and is indicated for the treatment and prevention of flea infestations and the treatment and control of *Ixodes scapularis* (black-legged tick) and *Amblyomma americanum* (lone star tick) infestations for one month in cats and kittens 8 weeks of age and older, and weighing 1.8 lbs or greater.

N. Emergency Authorized Use

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

O. Limitations of Authorized Use

NexGard® COMBO (esafoxolaner, eprinomectin, and praziquantel topical solution) is authorized for this use only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of NexGard® COMBO

(esafoxolaner, eprinomectin, and praziquantel topical solution) 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 0.055 mL/lb (0.12 mL/kg), which delivers 0.65 mg/lb (1.44 mg/kg) esafoxolaner, 0.22 mg/lb (0.48 mg/kg) eprinomectin and 4.53 mg/lb (9.98 mg/kg) praziquantel dose, given topically. The Corrected FOI Summary for the original approval of NADA 141-570, dated April 20, 2023, contains dosage characterization information for cats.

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® COMBO may be effective for the treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in cats and kittens based on data from a laboratory effectiveness study. The evidence supporting effectiveness is based on a placebo-controlled laboratory effectiveness study with an induced New World screwworm (NWS) infestation using NexGard® COMBO in cats. The data support that it is reasonable to believe that NexGard® COMBO may be effective for the treatment of infestations caused by NWS (*C. hominivorax*) larvae (myiasis) in cats and kittens.

Laboratory Effectiveness Study:

Title: Evaluation of the Efficacy of a Single Topical Treatment of NexGard® COMBO in Cats Artificially Infested with Larvae of *Cochliomyia hominivorax*. (Study No. 2023-3653)

Study Dates: May 28, 2025 to July 16, 2025

Study Location: Rio de Janeiro, Brazil

Study Design:

Objective: To evaluate the effectiveness of NexGard® COMBO when applied once topically at the labeled dose for the treatment of induced infestations of *C. hominivorax* first stage instar larvae in cats.

Study Animals: Fourteen cats (6 males and 8 females), 14 to 131 months of age and weighing 2.8 to 5.7 kg.

Experimental Design: This study was conducted in accordance with Good Clinical Practice (GCP) guidelines and followed a randomized block design based on body weight. Animals were included in a phased manner with two to four cats in each phase of the study, and were infested with approximately 50 viable first stage instar

larvae of *C. hominivorax* on Day -1. Cats were randomized to either an untreated control or a NexGard® COMBO group; there were seven cats in each group.

Drug Administration: Drug administration was on Day 0. Cats in the control group were untreated. Cats in the treatment group were topically administered 0.9 mL NexGard® COMBO, as per label. Esafoxolaner doses ranged from 2.2 to 3.8 mg/kg (approved dose range = 1.44 to 4.3 mg/kg). The dose was administered as a single spot applied directly on the skin in the midline of the neck, between the base of the skull and the shoulder blades.

Measurements and Observations: *C. hominivorax* larvae expelled from the wound were counted and categorized as live or dead on Day 0 at 15, 30, and 45 minutes; and at 1 through 6, 12, and 24 hours after treatment. On Day 1 (24 hours post-treatment), cats were anesthetized and the remaining *C. hominivorax* larvae were manually collected from the wound, categorized as live or dead, and counted.

Statistical Methods:
Effectiveness was determined based on the percent reduction in live, recovered *C. hominivorax* larvae counts on Day 1 in the NexGard® COMBO group compared to the control group.

Percent Effectiveness = 100 x (cc - ct)/cc

Where cc = Arithmetic mean of live, recovered larvae counts in the control group
ct = Arithmetic mean of live, recovered larvae counts in the NexGard® COMBO group

Results:

1. **Expelled** Live and Dead Larval Counts:
   One cat treated with NexGard® COMBO started expelling live and dead larvae at 15 minutes post-treatment. Another treated cat started expelling dead larvae at 45 minutes post-treatment. Thereafter, treated cats expelled live larvae from 1 through 5 hours post-treatment and expelled dead larvae throughout the end of the study. With the exception of three control cats that each expelled one live larva at 45 minutes, and 1 and 6 hours post-treatment, no control cats expelled any dead or live larvae throughout the study.

2. **Recovered** Larvae on Day 1:
   All cats had recovered larvae on Day 1. In the control group, no dead larvae were recovered and the number of live, recovered larvae ranged from 11 to 22 (arithmetic mean = 16.6). In the treated group, no live larvae were recovered and the number of dead, recovered larvae ranged from 2 to 12 (arithmetic mean = 5.7). The percent effectiveness of NexGard® COMBO based on the reduction in live, recovered larvae counts was 100%.

Adverse Reactions: No adverse reactions were reported.

Conclusions:
The results of the study demonstrate NexGard® COMBO may be effective for the treatment of infestations caused by New World screwworm (*Cochliomyia*

hominivorax) larvae (myiasis) in cats and kittens. The study had the following limitations:

- Only first instar larvae were evaluated, which may be more susceptible to insecticidal agents than the larger third instar larvae seen in more advanced cases.[1]
- The study had small, aseptically created wounds when naturally occurring wounds can vary in size and severity and can have secondary bacterial infections.
- This study used the labeled dose band, resulting in esafoxolaner doses of 2.2 to 3.8 mg/kg. It did not test the minimum point dose (1.44 mg/kg).

III. TARGET ANIMAL SAFETY

FDA did not require target animal safety studies for this authorization. The Corrected FOI Summary for the original approval of NADA 141-570, dated April 20, 2023, contains a summary of target animal safety studies for cats. The safety of NexGard® COMBO has not been evaluated in cats less than 8 weeks of age or less than 1.8 lbs. It is reasonable to believe that the known and potential benefits of NexGard® COMBO outweigh the known and potential risks for cats of all ages and weights because NWS myiasis is potentially fatal in cats if left untreated, therefore justifying including cats less than 8 weeks of age or less than 1.8 lbs in this authorization.

IV. HUMAN FOOD SAFETY

This drug is intended for use in cats. 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 and package insert contain the following information regarding safety to humans handling, administering, or exposed to NexGard® COMBO:

Not for human use. Keep this and all drugs out of sight and reach of children.

Avoid direct contact with application site for 4 hours or until visibly dry.

This product may act as a mild to moderate eye irritant.

Keep product in the original packaging until use. Wash hands after product administration. If the product accidentally gets into the eyes, rinse thoroughly with water. If wearing contact lenses, flush the eyes first with water and then remove the lenses and continue to flush thoroughly with water. In case of accidental ingestion, or if skin or eye irritation occurs, contact a poison control center or physician for treatment advice.

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[1] Han, Hock Siew et al. "The Comparative Efficacy of Afoxolaner, Spinosad, Milbemycin, Spinosad plus Milbemycin, and Nitenpyram for the Treatment of Canine Cutaneous Myiasis." *Veterinary dermatology*. 29.4 (2018): 312-e109.

VI. AGENCY CONCLUSIONS

Based on the totality of scientific evidence available to FDA, including data from a laboratory effectiveness study, it is reasonable to believe that NexGard® COMBO, when used as authorized, may be effective for the treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in cats and kittens. The known and potential benefits of NexGard® COMBO (i.e., treating a potentially fatal disease), when used as authorized, outweigh the known and potential risks associated with use of the drug. Finally, there is no adequate, approved, and available alternative to the product because there are no approved products for the treatment of New World screwworm (myiasis) in cats and kittens.

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).