

Fact Sheet for Veterinarians: Emergency Use Authorization of NexGard COMBO (esafoxolaner, eprinomectin, and praziquantel topical solution) for New World Screwworm (NWS)

NexGard COMBO (esafoxolaner, eprinomectin, and praziquantel topical solution)

Topical solution
For topical use in cats

Original EUA Authorized Date: 02/18/2026

Emergency Use Authorization for NexGard COMBO (esafoxolaner, eprinomectin, and praziquantel topical solution) 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 COMBO (esafoxolaner, eprinomectin, and praziquantel topical solution) for the treatment of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) in cats and kittens. NexGard COMBO is not approved for this use.

NexGard COMBO (esafoxolaner, eprinomectin, and praziquantel topical solution) (NADA 141-570) is approved for other uses in cats and kittens.¹

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.

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

¹ NexGard COMBO 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.

- 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 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, 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 COMBO (esafoxolaner, eprinomectin, and praziquantel topical solution) package insert for full **Product Description** information.

Dosage and Administration

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

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>

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>

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

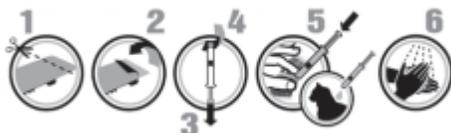
NexGard COMBO should be used in conjunction with the mechanical removal of larvae (live and dead) remaining in the wound after treatment (see **Precautions**).

Dosage 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.



1. Use scissors to cut the blister along the dotted line.
2. Then pull the lid away.
3. Remove the applicator from the package and hold it upright. Pull back the plunger slightly.
4. Twist and pull off the cap.
5. Part the hair on the midline of the neck, between the base of the skull and the shoulder blades until the skin is visible. Place the tip of the applicator on the skin and apply the entire contents directly onto the skin in one spot. The product should be applied to dry skin on an area where the cat cannot lick it off. If the weight of the cat requires a second application, apply the contents in the same manner as described above in the same location.
6. Wash hands after use with soap and water.

Risk-Benefit Consideration for Cats on Other Isoxazolines:

If a cat is currently receiving another isoxazoline product for routine ectoparasite control, veterinarians should consider administering NexGard COMBO to cats 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 a laboratory effectiveness study, it is reasonable to believe that NexGard COMBO (esafoxolaner, eprinomectin, and praziquantel topical solution) may be effective for the treatment of infestations

caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) in cats and kittens, and when used under the conditions described in the authorization, the known and potential benefits of NexGard COMBO (esafoxolaner, eprinomectin, and praziquantel topical solution) outweigh the known and potential risks.

1. Laboratory Effectiveness Study:

Title/Objective: 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 Design:

Fourteen healthy cats (2.8 to 5.7 kg, 14 to 131 months old) were enrolled. On Day -1, each cat received a 2 cm surgical wound on the right neck and the wounds were infested with 50+ *Cochliomyia hominivorax* first instar (L1) larvae. On Day 0, cats were allocated into two groups and either treated with 0.9 mL NexGard COMBO (the labeled dose) or left untreated. On Day 0, every 15 minutes for the first hour, and at 1 through 6, 12, and 24 hours after treatment, *C. hominivorax* larvae expelled from the wound were counted and categorized as live or dead. Expelled larvae in cage trays were also counted. On Day 1 (24 hours post-treatment), cats were anesthetized and the remaining *C. hominivorax* larvae were manually recovered from the wound, categorized as live or dead, and counted. The wounds were cleaned and treated with an antibiotic ointment.

Results:

a. 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 until 5 hours post-treatment and dead larvae until the end of the study. With the exception of three separate 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.

b. 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%.

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.⁵
- 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 2.2-3.8 mg/kg. It did not test the minimum point dose (1.44 mg/kg).

Contraindications

There are no known contraindications for the use of NexGard COMBO.

Human Warnings

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.

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

Precautions

Esafoxolaner, one of the ingredients in NexGard COMBO, 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 cats receiving isoxazoline class drugs, even in cats without a history of seizures. Use with caution in cats with a history of seizures or neurologic disorders.

Do not administer orally. Cats may salivate excessively if NexGard COMBO is accidentally administered orally or is ingested through licking/grooming the application site (see **Target Animal Safety** in the package insert).

The safety of NexGard COMBO has not been fully evaluated in breeding, pregnant, or lactating cats.

The safety and effectiveness of NexGard COMBO has not been tested in kittens less than 8 weeks of age or weighing less than 1.8 lbs (0.8 kg).

⁵ 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.

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

Adverse Reactions

Refer to the package insert for full prescribing information, including **Target 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 COMBO (esafoxolaner, eprinomectin, and praziquantel topical solution) 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 COMBO (esafoxolaner, eprinomectin, and praziquantel topical solution) 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**.

⁶ 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

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 the 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. Cats may become reinfested following treatment.

Clients should be advised that:

- Gloves should be worn if cleaning the wound, or the cat's bedding, or disposing of larvae.
- Cats 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 cat 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 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.

Storage Information

Store at 59° – 86°F (15° – 30°C). Brief periods up to 104° F (40° C) are permitted. Protect from light.

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

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