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

Revised 02/2026

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

For topical use in cats only

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

Description:
NexGard® COMBO is a topical solution containing esafoxolaner, eprinomectin and praziquantel available in 0.3 mL and 0.9 mL unit applicators to treat cats from 1.8 lbs to 33 lbs. Each mL of NexGard® COMBO contains 12 mg of esafoxolaner, 4 mg of eprinomectin, and 83 mg of praziquantel. Inactive ingredients: dimethyl isosorbide, unstabilized glycerol formal, and butylated hydroxytoluene.

Esafoxolaner is a member of the aryl isoxazoline class of compounds. Its chemical name is 4-[(5S)-5-[3-chloro-5-(trifluoromethyl)phenyl]-5-(trifluoromethyl)-4, 5-dihydro-1,2-oxazol-3-yl]-N-{2-oxo-2-[(2,2,2-trifluoroethyl) amino]ethyl}-1-naphthamide.

Eprinomectin belongs to the avermectin class of anthelmintics and is a mixture of homologous components referred to as eprinomectin B1a and B1b. The chemical name for eprinomectin B1a is (4″R)-acetylamino-5-O-demethyl-4″-deoxyavermectin A_{1a}. The chemical name for eprinomectin B1b is (4″R)-acetylamino-5-O-demethyl-25-de(1-methylpropyl)-4″-deoxy-25-(1-methylethyl) avermectin A_{1a}.

Praziquantel is a pyrazinoisoquinoline anthelmintic. Its chemical name is 2-(Cyclohexylcarbonyl)- 1,2,3,6,7,11b-hexahydro-4H-pyrazino[2,1-a]-isoquinolin-4-one.

Indications:
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.

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.

For heartworm disease prevention, apply once monthly for at least three months after last exposure to mosquitoes (see **Effectiveness**).

Administer the entire contents of a NexGard® COMBO unit applicator topically once a month as specified in the following table:

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.

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.

Heartworm Prevention:
For the prevention of heartworm disease, NexGard® COMBO should be administered once a month year-round. At a minimum, administration of NexGard® COMBO should start at least 1 month before the cat's first expected exposure to mosquitoes and monthly thereafter until at least 3 months after the cat's last seasonal exposure to mosquitoes (see **Effectiveness**). If a dose is missed and a 30-day interval between doses is exceeded, administer NexGard® COMBO immediately and resume the monthly dosing schedule. Treatment with fewer than 3 monthly doses may not provide complete heartworm prevention. When replacing another monthly heartworm preventive product in a heartworm prevention program, the first treatment with NexGard® COMBO should be given within one month of the last dose of the former medication. At the discretion of the veterinarian, cats older than 6 months of age may be tested to determine the presence of existing heartworm infection before treatment with NexGard® COMBO. Cats already infected with adult heartworms can be given NexGard® COMBO monthly to prevent further infections.

Flea Treatment and Prevention:
For the treatment and prevention of flea infestations, the use of NexGard® COMBO may begin at any time of year. NexGard® COMBO should be administered year-round at monthly intervals or begin at least one month before fleas become active. However, an environmental infestation may persist for a short time after beginning treatment with NexGard® COMBO because of the development of adult fleas from eggs that were laid prior to the initiation of treatment.

Tick Treatment and Control:
For the treatment and control of infestations with *Ixodes scapularis* and *Amblyomma americanum*, the use of NexGard® COMBO may begin at any time of year. NexGard® COMBO should be administered year-round at monthly intervals or begin at least one month before the ticks become active.

Treatment and Control of Roundworms, Hookworms, and Tapeworms:
NexGard® COMBO provides treatment and control of roundworms (adult and fourth stage larval *Toxocara cati*), hookworms (adult and fourth stage larval *Ancylostoma tubaeforme*; adult *Ancylostoma braziliense*), and tapeworms (*Dipylidium caninum*). For the treatment of hookworm, roundworms and tapeworm infections, NexGard® COMBO should be administered once as a single dose. Monthly use of NexGard® COMBO will control any subsequent infections. Cats may be exposed to and can become infected with roundworms, hookworms, and tapeworms throughout the year, regardless of season or climate.

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.

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**).

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

The safety 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).

Adverse Reactions:
In a field safety and effectiveness study, which included a total of 201 households and 380 treated cats (244 cats treated with NexGard® COMBO, 136 cats treated with an active control), the safety of NexGard® COMBO was evaluated over a 90-day period through in-clinic physical examinations or through reporting of abnormalities by the owner.The most frequently reported reactions in the NexGard® COMBO and active control groups are presented in the following table.

Adverse Reactions by Treatment Group

EVENT	Treatment Group			
	NexGard COMBO		Active Control	
	n[1]	% (n=244)	n[2]	% (n=136)
Vomiting	16	6.56	8	5.88
Application Site Hair Change	9	3.69	0	0.00
Anorexia	7	2.87	4	2.94
Lethargy	6	2.46	5	3.68
Bacterial Skin Infection	4	1.64	1	0.74
Itching	4	1.64	0	0.00
Sneezing	4	1.64	5	3.68
Skin Peeling	3	1.23	2	1.47
Diarrhea	3	1.23	3	2.21
Epiphora	3	1.23	1	0.74
Hypersalivation	3	1.23	0	0.00
Hyperthermia	3	1.23	0	0.00
Alopecia	2	0.82	0	0.00
Dermal Thickening	2	0.82	0	0.00
Ear Pruritus	2	0.82	1	0.74
Application Site Redness	2	0.82	0	0.00
Conjunctivitis	1	0.41	1	0.74

[1]Number of cats treated with NexGard® COMBO with the identified abnormality.
[2]Number of cats treated with Active Control with the identified abnormality.

Contact Information:
To report suspected adverse events, for technical assistance or to obtain a copy of the SDS, contact Boehringer Ingelheim Animal Health USA Inc. at 1-888-637-4251 or www.nexgardforpets.com.

For additional information about reporting adverse drug experiences for animal drugs, contact FDA at 1-888-FDA-VETS or online at www.fda.gov/reportanimalae.

The Safety Data Sheet (SDS) provides additional occupational safety information. For customer service or to obtain product information, including the SDS, call 1-888-637-4251.

Clinical Pharmacology:
Mode of Action:
Esafoxolaner is a member of the isoxazoline family, shown to bind at a site to inhibit insect and acarine ligand-gated chloride channels, in particular those gated by the neurotransmitter gamma-aminobutyric acid (GABA), thereby blocking pre- and post-synaptic transfer of chloride ions across cell membranes. Prolonged esafoxolaner-induced hyperexcitation results in uncontrolled activity of the central nervous system and death of insects and acarines. The selective toxicity of esafoxolaner between insects/acarines and mammals may be inferred by the differential sensitivity of the insects/acarines' GABA receptors versus mammalian GABA receptors.

Eprinomectin is an endectocide in the macrocyclic lactone class that binds to glutamate gated chloride channels that are present in invertebrate nerve and muscle cells and increases the permeability of the cell membrane to chloride ions that triggers hyperpolarization of the nerve or muscle cell in susceptible parasites, resulting in paralysis and death of the parasite.

Praziquantel's mode of action is not precisely known, but treated tapeworms undergo muscular paralysis accompanied by a rapid influx of calcium ions and the disruption of the tegument.

Pharmacokinetics:
After a single topical administration to healthy male and female cats of a combined topical formulation containing esafoxolaner (12 mg/mL), eprinomectin (4 mg/mL), and praziquantel (83 mg/mL), at dose volumes of 0.06, 0.12, or 0.24 mL/kg, there was a dose proportional increase in the exposure of each ingredient based on maximum plasma concentration (Cmax) and area under the plasma concentration time curve (AUC). After repeated monthly doses of the combined topical formulation at the target dose of 1.44 mg/kg esafoxolaner, 0.48 mg/kg eprinomectin, and 9.98 mg/kg praziquantel, steady state was reached by the fourth dose for esafoxolaner and after the second dose for eprinomectin and praziquantel. Additionally, modest accumulation was observed for esafoxolaner (approximately 3-fold) and praziquantel (approximately 1.5- to 2-fold) between the first and fifth dose, whereas no accumulation was observed for eprinomectin.

Effectiveness:
Heartworm Prevention:
In well-controlled laboratory studies, NexGard® COMBO (esafoxolaner, eprinomectin, and praziquantel topical solution) was 100% effective in preventing the development of heartworms in cats inoculated with infective larvae of *Dirofilaria immitis* 30 days prior to the first of three consecutive monthly treatments.

Flea Treatment and Prevention:
In a well-controlled laboratory study, NexGard® COMBO killed >92% of fleas within 24 hours. During subsequent weekly infestations, NexGard® COMBO killed ≥95.5% of fleas within 24 hours through Day 31 and killed fleas before they could lay eggs. The effectiveness against adult fleas at 24 hours post-infestation in the treated cats virtually eliminated flea egg production (99.8 – 100% control of flea egg production by 24 hours) throughout the remainder of the month. In a field safety and effectiveness study in the United States, conducted in households with existing flea infestations, the effectiveness of NexGard® COMBO against fleas was 97.8%, 99.6%, and 99.9% when assessed on Days 30, 60, and 90, respectively. Cats with signs of flea allergy dermatitis showed improvement in alopecia, dermatitis/pyodermatitis, pruritus, erythema, papules, and scaling, as a direct result of eliminating fleas.

Tick Treatment and Control:
In well-controlled laboratory studies, NexGard® COMBO demonstrated ≥95.1% effectiveness against *Ixodes scapularis* 48 hours post-infestation for a month and ≥95.6% effectiveness against *Amblyomma americanum* 72 hours post-infestation for a month.

Treatment and Control of Roundworms, Hookworms, and Tapeworms:
In 2 well-controlled laboratory studies, NexGard® COMBO provided 98.9% and 100% effectiveness against natural and/or induced roundworm infections with the dose-limiting gastrointestinal nematode species (adult *Toxocara cati*), respectively. Effectiveness studies against fourth stage larval *Toxocara cati* and hookworms (adult and fourth stage larval *Ancylostoma tubaeforme*; adult *Ancylostoma braziliense*) were conducted with an early formulation. The doses of eprinomectin in this early formulation are equivalent to that of the final formulation of NexGard® COMBO. In well-controlled laboratory studies, NexGard® COMBO provided on average 92.8% effectiveness against natural and/or induced infections with *Dipylidium caninum*.

Target Animal Safety:
Margin of Safety Study:
NexGard® COMBO was applied topically to healthy kittens (8 to 9 weeks of age) at 1X, 3X, or 5X the maximum exposure dose six times at 28-day intervals; kittens in the control group were dosed with mineral oil. One kitten in the 5X group exhibited recumbency, tremors, hypothermia, ataxia, disorientation, and pupil dilation (responsive to light) 9 hours after the third dose. This kitten received supportive care, including washing the application site, and recovered within 48 hours post-dose. During necropsy, a dark red subcutaneous area (≤5 mm diameter) was observed in the treatment site area of three cats in the 5X group, but microscopic examination revealed no histologic abnormalities. No significant changes related to NexGard® COMBO were observed for physical examination, body weight, clinical pathology (hematology, coagulation, and serum chemistry), histopathology, or organ weights.

Study in Heartworm Positive Cats:
Adult cats, 4.7 to 6.6 months of age, were experimentally infected with adult heartworms (*D. immitis*) by venous transplantation. All cats were negative for heartworm antibody, antigen and microfilariae prior to transplantation. Two weeks after transplantation, immunoserology verified positive antigen and the presence of microfilariae in all enrolled cats. A combination of fipronil, eprinomectin, praziquantel, and (S)-methoprene was applied topically to cats at 1X or 3X the maximum exposure dose once every 28 days for three consecutive treatments; cats in the control group were dosed with mineral oil. One cat in the 1X group exhibited cyanotic mucous membranes and tachypnea for 24 hours following the first treatment. The cat recovered and exhibited no abnormal signs following two subsequent treatments. There was no difference between the treatment groups in the number of adult *D. immitis* recovered at the end of the study.

Oral Administration Study:
Oral tolerance was evaluated to assess the effects of accidental oral ingestion. Kittens (male and female) ranging in age from 7.4 to 8.9 weeks were orally administered NexGard® COMBO at 1X the maximum exposure dose; kittens in the control group were dosed with saline. Cats were observed for adverse reactions at 1, 2, 3, 4, and 8 hours following administration, then twice a day until Day 14. All 8 cats administered NexGard® COMBO immediately exhibited excessive hypersalivation after oral administration. However, all cats stopped salivating within 1 hour after exposure. No additional health-related observations were seen for the remainder of the study.

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.

Approved by FDA under NADA # 141-570

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

NexGard® is a registered trademark and NEXGARD COMBO is a trademark of Boehringer Ingelheim Animal Health France, used under license.

184238-003 Rev. 04/2023
US-PET-0187-2023-V2

Boehringer Ingelheim

U.S. FOOD & DRUG ADMINISTRATION

February 18, 2026

Boehringer Ingelheim Animal Health USA, Inc.
Attention: Tracy L. Robertson
Regulatory Affairs, Operations
3239 Satellite Blvd.
Duluth, GA 30096

Re: Emergency Use Authorization 006686

Dear Ms. Robertson:

This letter is in response to the request by Boehringer Ingelheim Animal Health USA, Inc. (Boehringer) that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for the emergency use of NexGard COMBO (esafoxolaner, eprinomectin, and praziquantel topical solution) for the treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in cats and kittens, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. § 360bbb-3).

On August 18, 2025, pursuant to Section 564(b)(1)(C) of the FD&C Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is 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 New World screwworm (*Cochliomyia hominivorax*) (hereinafter "NWS"). On the basis of such determination, the Secretary of HHS on August 18, 2025 declared that circumstances exist justifying the authorization of emergency use of animal drugs to treat or prevent NWS myiasis in animals, pursuant to section 564(b)(1) of the FD&C Act, subject to terms of any authorization issued under that section.[1]

NexGard COMBO is a topical antiparasitic that is indicated under NADA 141-570 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 also indicated under NADA 141-570 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. NexGard COMBO is not approved for the treatment of NWS larvae (myiasis).

Based on the totality of scientific evidence available to the FDA, including data from a laboratory effectiveness study, it is reasonable to believe that NexGard COMBO may be effective for the treatment of infestations caused NWS larvae (myiasis) in cats and kittens, as described in this

[1] 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, and when used under the conditions described in this authorization, the known and potential benefits of NexGard COMBO outweigh the known and potential risks of such product for cats of all ages and weights because NWS is potentially fatal in cats if left untreated, therefore justifying including cats less than 8 weeks of age and less than 1.8 lbs in this authorization.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the FD&C Act are met, I am authorizing the emergency use of NexGard COMBO for the treatment of infestations caused by NWS larvae (myiasis) in cats and kittens, as described in this authorization and subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of NexGard COMBO for the treatment of infestations caused by NWS larvae (myiasis) in cats and kittens, when administered as described in this authorization, meets the criteria for issuance of an authorization under Section 564(c) of the FD&C Act, because:

1. NWS can cause a serious or life-threatening disease or condition to animals and humans;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that NexGard COMBO may be effective in treating NWS and that, when used under the conditions and within the scope described in this authorization, the known and potential benefits of NexGard COMBO when used to treat NWS outweigh the known and potential risks of such product; and

3. There is no adequate, approved, and available alternative[2] to the emergency use of NexGard COMBO for the treatment of infestations caused by NWS larvae (myiasis) in cats and kittens.[3]

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the FD&C Act, that the scope of this authorization is limited as follows:

- NexGard COMBO, as covered by this authorization, will be used only for the treatment of infestations caused by NWS larvae (myiasis) in cats and kittens by a veterinarian by prescription; and

- The use of NexGard COMBO covered by this authorization must be in accordance with the authorized Fact Sheet.

[2] There are no approved products for the treatment of New World screwworm (myiasis) in cats and kittens.
[3] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the FD&C Act.

Product Description

NexGard COMBO is a topical antiparasitic. The authorized NexGard COMBO carton labeling is clearly marked for the approved indications and for NWS under Emergency Use Authorization, with a website address and QR code that links to the authorized Fact Sheet.

NexGard COMBO should be stored at 59° – 86°F (15° – 30°C). Brief periods up to 104°F (40°C) are permitted. Protect from light.

NexGard COMBO is authorized to be accompanied by the following product-specific information pertaining to emergency use, which is required to be made available to veterinarians and others who may administer the product:

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

I have concluded, pursuant to Section 564(d)(2) of the FD&C Act, that it is reasonable to believe that the known and potential benefits of NexGard COMBO, when used for the treatment of infestations caused by NWS larvae (myiasis) in cats and kittens and used in accordance with this authorization, outweigh its known and potential risks.

I have concluded, pursuant to Section 564(d)(3) of the FD&C Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that NexGard COMBO may be effective for the treatment of infestations caused by NWS larvae (myiasis) in cats and kittens when used in accordance with this authorization, pursuant to Section 564(c)(2)(A) of the FD&C Act.

Having reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, I have concluded that NexGard COMBO, as described in this authorization, meets the criteria set forth in Section 564(c) of the FD&C Act concerning safety and potential effectiveness.

The emergency use of this product under an EUA must be consistent with, and may not exceed, the terms of this authorization, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section III). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) of the FD&C Act described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1) of the FD&C Act, NexGard COMBO is authorized for the treatment of infestations caused by NWS larvae (myiasis) in cats and kittens as described in this authorization, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

III. Conditions of Authorization

Pursuant to Section 564 of the FD&C Act, I am establishing the following conditions on this authorization:

A. Boehringer will ensure that the authorized NexGard COMBO, accompanied with the authorized Fact Sheet, is distributed to veterinary facilities[4] and veterinarians, or authorized distributor(s)[5], consistent with the terms and conditions of this EUA, and that authorized distributor(s) will limit distribution to other authorized distributors and end users.

B. Boehringer will ensure that if a sticker is used on the labeling, that the sticker contains a website address and QR code that link to the authorized Fact Sheet and that the sticker is placed in a blank space or does not obscure any important use or safety information.

C. Boehringer and authorized distributor(s) will ensure that appropriate storage is maintained until the product is delivered to veterinary facilities and veterinarians.

D. Boehringer and authorized distributor(s) will ensure that the terms and conditions of this EUA are made available to all relevant stakeholders (e.g., U.S. government agencies, state and local government authorities, authorized distributors, veterinary facilities, and veterinarians) involved in distributing or receiving authorized NexGard COMBO. Boehringer will provide to all relevant stakeholders a copy of this Letter of Authorization and communicate any subsequent amendments that might be made to this Letter of Authorization and its authorized accompanying materials (e.g., its authorized Fact Sheet).

E. Boehringer may request changes to this authorization, including to the authorized Fact Sheet for NexGard COMBO. Requests for changes should be submitted to the Office of New Animal Product Evaluation. Such changes require appropriate authorization prior to implementation.[6]

F. Reporting Adverse Drug Experiences and Product/Manufacturing Defects:

   Boehringer will fully comply with the reporting requirements under 21 CFR 514.80. When collecting adverse event information, Boehringer will attempt to determine whether the use of NexGard COMBO was related to the EUA and will put this categorization, as well as the reason for use, in the narrative description of the adverse event. Boehringer will submit the reports electronically using either of the options that are described on FDA's Veterinary Adverse Event Reporting for Manufacturers webpage (www.fda.gov/IndustryReportAnimalAE).

   Submitted reports should state in the "Narrative of Adverse Event" field: "NexGard COMBO use for NWS under an EUA". Contact the Pharmacovigilance Liaison in CVM's Division of Pharmacovigilance and Surveillance at CVMAESupport@fda.hhs.gov for any questions

[4] Veterinary facilities include veterinary hospitals, veterinary clinics and other establishments providing veterinary care. If a veterinarian is not associated with a veterinary facility, the veterinarian then assumes the obligations of the veterinary facility.
[5] The term "distributors" includes all parties in the supply chain between the recipient of this authorization letter and the end user. "Authorized distributors" are all distributors who otherwise lawfully obtain and distribute the product, unless Boehringer places limits on distribution in writing (e.g., via contract or written notice accompanying the product).
[6] Revisions that do not necessitate revision to this letter (e.g., changes to the Fact Sheet, specified cGMPs, expiration dating extensions) may be authorized through separate notification without reissuance of this letter.

related to electronic reporting or for assistance with setting up a Safety Reporting Portal account.

G. Through a process of inventory control, Boehringer and authorized distributor(s) will maintain records regarding distribution of the authorized NexGard COMBO (i.e., lot numbers, quantity, receiving site, receipt date).

H. Boehringer and authorized distributor(s) will maintain records in connection with this EUA 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, and will make such records available to FDA for inspection upon request.

I. Boehringer will comply with all other FD&C Act requirements applicable to the approved product, NexGard COMBO, including, but not limited to, requirements related to registration and listing, drug quality, and manufacturing process, facilities, and equipment in accordance with the approved application[7], unless such requirement is specifically waived or modified for the authorized product in this authorization. Boehringer shall update their drug listing to reflect the EUA, including submission of updated labeling, before commercial distribution of the EUA product begins.

Conditions of Authorization for Veterinary Facilities and Veterinarians

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

K. Veterinary facilities and veterinarians receiving NexGard COMBO will track serious adverse events potentially related to NexGard COMBO use under this EUA and must report these to FDA in accordance with the Fact Sheet for Veterinarians. Report by (1) contacting Boehringer at 1-888-637-4251, (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. Include the statement “NexGard COMBO use for NWS under an EUA” under the “Describe Adverse Event/Product Problem/Product Use Error” heading, followed by a detailed account of the adverse event.

L. 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 coadministered. 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.

M. Veterinary facilities will maintain any records associated with this EUA for at least two years following the termination of the declaration or the revocation of the authorization, or until

[7] Changes shall be submitted and approved in accordance with 21 CFR 514.8, unless otherwise approved under Paragraph E of this letter.

notified by HHS or FDA, whichever is sooner. Such records will be made available to Boehringer, HHS, and FDA for inspection upon request.

Conditions of Authorization Related to Advertisements and other Promotional Descriptive Printed Matter

N. All advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter, relating to the authorized use of NexGard COMBO shall be consistent with the authorized Fact Sheet[8], and the terms set forth in this EUA, as well as comply with FD&C Act sections 502(a) and 502(n), and 21 CFR Part 202. Additionally, the sponsor and authorized distributor(s) shall comply with any other applicable requirements in the FD&C Act and its implementing regulations regarding advertising and/or promotion.

O. Boehringer and authorized distributor(s) may not imply that NexGard COMBO is FDA approved or conditionally approved for the authorized use by making statements such as "NexGard COMBO is safe and effective for the treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in cats and kittens". Boehringer and authorized distributor(s) may disseminate advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter relating to the emergency use of NexGard COMBO that provide accurate descriptions of safety and effectiveness information summarized in the authorized Fact Sheet. Such materials must include any limitations of information submitted to support this authorization.

P. All advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter relating to the authorized use of NexGard COMBO shall be accompanied by the authorized Fact Sheet and the applicable approved labeling (e.g., package insert), and shall clearly and conspicuously state that:

- NexGard COMBO has not been approved for the treatment of infestations caused by NWS larvae (myiasis) in cats and kittens;
- NexGard COMBO has been authorized by FDA under an EUA for the treatment of infestations caused by NWS larvae (myiasis) in cats and kittens; and
- NexGard COMBO is authorized as described herein only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of NexGard COMBO under Section 564(b)(1) of the FD&C Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or the authorization is revised or revoked sooner.

Q. All advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter must be submitted to the CVM OSC DER eSubmitter Program at the time of initial dissemination (publication or broadcast). Each submission of promotional labeling or advertisements must be accompanied by a completed Form FDA 2301.

[8] If the authorized Fact Sheet references sections of a drug's FDA-approved labeling, the entirety of each section is considered part of the authorized Fact Sheet, except as otherwise specified. Advertising and promotional materials may not use general references to approved labeling in lieu of summarizing or restating its contents when a summary or restatement is otherwise needed to comply with applicable requirements.

If FDA notifies Boehringer or authorized distributor(s) that any descriptive materials, advertising, or promotional materials do not meet the terms set forth in this EUA, Boehringer or authorized distributor(s) must discontinue and/or cease distribution of such advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter in accordance with FDA's notification. Furthermore, as part of its notification, FDA may also require Boehringer or authorized distributor(s) to issue corrective communication(s).

IV. Duration of Authorization

This EUA will be effective as described herein until the declaration that circumstances exist justifying the authorization of the emergency use of animal drugs during the NWS public health emergency is terminated under Section 564(b)(2) of the FD&C Act or the EUA is revised or revoked under Section 564(g) of the FD&C Act.

Sincerely,

{see appended electronic signature page}
Timothy Schell, Ph.D.
Director
Center for Veterinary Medicine
U.S. Food and Drug Administration

Enclosures:
Freedom of Information Summary
Fact Sheet

Electronic Signature Addendum for Submission ID

V-006686-A-0000-OT

Signing Authority (Role)	Letter Date
Timothy Schell (Center Director)	2/18/2026

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