

HOW TO GET YOUR \$50 REBATE CHECK

ORIGINAL ITEMIZED RECEIPT MUST ACCOMPANY FORM AND BE DATED ON OR BEFORE 12/31/2015. ONE COUPON REQUIRED FOR EVERY JOINT PURCHASE OF 12 HEARTGARD BRAND PRODUCT AND 6 FLEA & TICK PRODUCT DOSES. PLEASE ALLOW 6 TO 8 WEEKS FOR DELIVERY. REBATE REQUEST MUST BE RECEIVED ON OR BEFORE 03/01/2016. OFFER CANNOT BE COMBINED WITH ANY OTHER COUPON OFFER.

PET OWNER, PLEASE PRINT THE FOLLOWING INFORMATION:

Name: _____

Address: _____

City: _____ State: _____ Zip: _____

Email: _____

Pet's Name: _____ Pet's Birthday (MM/DD/YY) ____/____/____

Merial respects your privacy. We will not share, sell or rent the information you provide on this form. By providing your email address, you agree to receive special coupons, offers and information from Merial.

Product must be dispensed on or before 12/31/2015 | Rebate request must be received on or before 3/1/2016

Complete the following for your \$50 Rebate Check:

- | | | |
|--|---|----------|
| <input type="checkbox"/> HEARTGARD® Plus (ivermectin/pyrantel) | <input type="checkbox"/> FRONTLINE® Plus For Dogs <input type="checkbox"/> FRONTLINE Plus For Cats | 15-20825 |
| <input type="checkbox"/> HEARTGARD (ivermectin) | <input type="checkbox"/> FRONTLINE TRITAK® For Dogs <input type="checkbox"/> FRONTLINE TRITAK For Cats | 15-20827 |
| | <input type="checkbox"/> NexGard® (afoxolaner) | 15-20826 |

FOR VETERINARY CLINIC USE ONLY:

Merial Account #: _____

Veterinary Hospital: _____

Address: _____

City: _____ State: _____ Zip: _____

MERIAL® Rewards #: _____ MERIAL Rewards Name: _____

Redeem this coupon by returning it to:

STAMP CLINIC INFORMATION HERE

Merial
Program Headquarters
PO Box 540069
El Paso, TX 88554-0069

PLEASE ALLOW 6-8 WEEKS FOR DELIVERY.

Original receipt must be included and dated on or before 12/31/2015. Rebate request must be received on or before 3/1/2016. Merial reserves the right to amend, substitute, or withdraw this offer at any time without notice. Receipts must indicate a HEARTGARD Brand Product 12-Pack purchase and a 6-Pack of FRONTLINE Plus Brand Product, FRONTLINE TRITAK Brand Product, or NexGard. Offer may be redeemed only by pet owner. Good only in continental U.S. and Hawaii. Void where prohibited or restricted by law. All federal, state and local laws and regulations apply. This form must accompany request; reproductions or other copies will not be accepted. Fraudulent submission could result in Federal prosecution under mail fraud statutes (Title 18, United States Code, Section 1341 and 1342) and applicable state laws. May not be combined with any other offer.



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RECEIVE A \$50 REBATE

When you Buy 12 Doses of a HEARTGARD® (ivermectin) Brand Product* and 6 Doses of a flea & tick control product*



MANUFACTURER'S COUPON | ORIGINAL RECEIPT REQUIRED | FOR MAIL-IN REBATE REDEEMABLE ONLY ON PRODUCT BOUGHT AT YOUR VETERINARY CLINIC EXPIRES 12/31/2015 | MAY NOT BE COMBINED WITH ANY OTHER OFFER

*** of the same product in the same size at one time**

NexGard IMPORTANT SAFETY INFORMATION: For use in dogs only. The most common adverse reaction is vomiting. Other adverse reactions reported are dry/flaky skin, diarrhea, lethargy, and anorexia. The safe use of NexGard in pregnant, breeding, or lactating dogs has not been evaluated. Use with caution in dogs with a history of seizures.

NexGard[®] (afoxolaner) Chewables

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

Description: NexGard[®] (afoxolaner) is available in four sizes of beef-flavored, soft chewables for oral administration to dogs and puppies according to their weight. Each chewable is formulated to provide a minimum afoxolaner dosage of 1.14 mg/lb (0.5 mg/kg). Afoxolaner has the chemical composition 1-(4-hydroxybenzoyl)-5-isoxazolinyl-2-(2,2,2-trifluoroethyl)phenyl-4,5-dihydro-5-(1H-imidazol-2-yl)-3-isoxazolinyl-2-(2,2,2-trifluoroethyl)amino)pyridine.

Indications: NexGard kills adult fleas and is indicated for the treatment and prevention of flea infestations (*Ctenocephalides felis*), and the treatment and control of Black-legged tick (*Ixodes scapularis*), American Dog tick (*Dermacentor variabilis*), and Lone Star tick (*Amblyomma americanum*) infestations in dogs and puppies 6 weeks of age and older, weighing 4 pounds of body weight or greater, for one month.

Dosage and Administration: NexGard is given orally once a month, at the minimum dosage of 1.14 mg/lb (0.5 mg/kg).

Dosing Schedule:

| Body Weight | Afoxolaner Per Chewable (mg) | Chewables Administered |
|--------------------|---|------------------------|
| 4.0 to 10.0 lbs. | 11.3 | One |
| 10.1 to 24.0 lbs. | 28.3 | One |
| 24.1 to 60.0 lbs. | 68 | One |
| 60.1 to 121.0 lbs. | 136 | One |
| Over 121.0 lbs. | Administer the appropriate combination of chewables | |

NEXGARD can be administered with or without food. Care should be taken that the dog consumes the complete dose, and treated animals should be observed for a few minutes to ensure that part of the dose is not lost or refused. If it is suspected that any of the dose has been lost or if vomiting occurs within two hours of administration, re-dose with another full dose. If a dose is missed, administer NEXGARD and resume a monthly dosing schedule.

Flea Treatment and Prevention:

Treatment with NEXGARD may begin at any time of the year. In areas where fleas are common year-round, monthly treatment with NEXGARD should continue the entire year without interruption.

To minimize the likelihood of flea reinfestation, it is important to treat all animals within a household with an approved flea control product.

Tick Treatment and Control:

Treatment with NEXGARD may begin at any time of the year (see **Effectiveness**).

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.

Precautions:

The safe use of NEXGARD in breeding, pregnant or lactating dogs has not been evaluated. Use with caution in dogs with a history of seizures (see **Adverse Reactions**).

Adverse Reactions:

In a well-controlled US field study, which included a total of 333 household pets and 615 treated dogs (415 administered afoxolaner, 200 administered active control), no serious adverse reactions were observed with NEXGARD.

Over the 90-day study period, all observations of potential adverse reactions were recorded. The most frequent reactions reported at an incidence of > 1% within any of the three months of observations are presented in the following table. The most frequently reported adverse reaction was vomiting. The occurrence of vomiting was generally self-limiting and of short duration and tended to decrease with subsequent doses in both groups. Five treated dogs experienced anorexia during the study, and two of those dogs experienced anorexia with the first dose but not subsequent doses.

Table 1: Dogs With Adverse Reactions.

| | Treatment Group | | |
|-----------------------------------|---|--|----|
| | Afoxolaner N ¹ % (n=415) | Oral active control N ² % (n=200) | |
| Vomiting (with and without blood) | 17 | 4.1 | 25 |
| Dry/Flaky Skin | 13 | 3.1 | 2 |
| Diarrhea (with and without blood) | 13 | 3.1 | 7 |
| Lethargy | 7 | 1.7 | 4 |
| Anorexia | 5 | 1.2 | 9 |

¹Number of dogs in the afoxolaner treatment group with the identified abnormality.
²Number of dogs in the control group with the identified abnormality.

In the US field study, one dog with a history of seizures experienced a seizure on the same day after receiving the first dose and on the same day after receiving the second dose of NEXGARD. This dog experienced a third seizure one week after receiving the third dose. The dog remained enrolled and completed the study. Another dog with a history of seizures had a seizure 19 days after the third dose of NEXGARD. The dog remained enrolled and completed the study. A third dog with a history of seizures received NEXGARD and experienced no seizures throughout the study.

To report suspected adverse events, for technical assistance or to obtain a copy of the MSDS, contact Merial at 1-888-637-4251 or www.merial.com/rebrand. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VEIS or online at <http://www.fda.gov/AnimalVeterinary/SafetyHealth>.

Mode of Action:

Afoxolaner is a member of the isoxazolinone family, shown to bind to a binding 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 afoxolaner-induced hyperpolarization results in uncontrolled activity of the central nervous system and death of insects and acarines. The selective toxicity of afoxolaner between insects and acarines and mammals may be inferred by the differential sensitivity of the insects and acarines' GABA receptors versus mammalian GABA receptors.

Effectiveness:

In a well-controlled laboratory study, NEXGARD began to kill fleas four hours after initial administration and demonstrated >99% effectiveness at eight hours. In a separate well-controlled laboratory study, NEXGARD demonstrated 100% effectiveness against adult fleas 24 hours post-infestation for 35 days, and was > 99% effective at 12 hours post-infestation through Day 21, and on Day 35. On Day 28, NEXGARD was 81.1% effective 12 hours post-infestation. Dogs in both the treated and control groups that were infested with fleas on Day-1 generated flea eggs at 12- and 24-hours post-treatment (0-1 eggs and 1-17 eggs in the NEXGARD treated dogs, and 4-50 eggs and 0-18 eggs in the control dogs, at 12- and 24-hours, respectively). At subsequent evaluations post-infestation, fleas from dogs in the treated group were essentially unable to produce any eggs (0-1 eggs) while fleas from dogs in the control group continued to produce eggs (1-141 eggs).

In a 90-day US field study conducted in households with existing flea infestations of varying severity, the effectiveness of NEXGARD against fleas on the Day 30, 60 and 90 visits compared with baseline was 98.0%, 99.7%, and 99.9%, respectively.

Collectively, the data from the three studies (two laboratory and one field) demonstrate that NEXGARD kills fleas before they can lay eggs, thus preventing subsequent flea infestations after the start of treatment or existing flea infestations.

In well-controlled laboratory studies, NEXGARD demonstrated >94% effectiveness against *Dermacentor variabilis* and *Ixodes scapularis*, 48 hours post-infestation, and against *Amblyomma americanum* 72 hours post-infestation, for 30 days.

Animal Safety:

In a margin of safety study, NEXGARD was administered orally to 8- to 9-week-old Beagle puppies at 1, 3, and 5 times the maximum exposure dose (6.3 mg/kg) for three treatments every 28 days, followed by three treatments every 14 days, for a total of six treatments. Dogs in the control group were sham-dosed. There were no clinically-relevant effects related to treatment on physical examination, body weight, food consumption, clinical pathology (hematology, clinical chemistry, or coagulation tests), gross pathology, histopathology or organ weights. Vomiting occurred throughout the study, with a similar incidence in the treated and control groups, including one dog in the 5x group that vomited four hours after treatment.

In a well-controlled field study, NEXGARD was used concomitantly with other medications, such as vaccines, anthelmintics, antibiotics (including topicals), steroids, NSAIDs, anesthetics, and antihistamines. No adverse reactions were observed from the concomitant use of NEXGARD with other medications.

Storage Information:

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

How Supplied:

NEXGARD is available in four sizes of beef-flavored soft chew-coded packages of 1, 3 or 6 beef-flavored chewables.

NADA 141-406, Approved by FDA
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Duluth, GA 30096-4640 USA

Made in India.

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