

Happiness is powerful
flea and tick control.



IMPORTANT SAFETY INFORMATION: NexGard® is for use in dogs only. The most frequently reported adverse reactions included itching, vomiting, dry/flaky skin, diarrhea, lethargy, and lack of appetite. 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. For more information, see full prescribing information inside this brochure or visit www.NexGardForDogs.com.



SATISFACTION GUARANTEED.

Along with our FRONTLINE® Plus and HEARTGARD® Plus (ivermectin/pyrantel) pet health products, we want you to be completely satisfied with your NexGard experience. If you have any issues with NexGard, please call us directly at 1-877-602-PLUS (1-877-602-7587).

NexGard®
(afoxolaner) Chewables

¹ Data on File at Merial.

² Dryden MW. Flea and tick control in the 21st century, challenges and opportunities. *Vet Derm.* 2009;20:435-440.

³ Blagburn BL, Dryden MW. Biology, treatment and control of flea and tick infestations. *Vet Clin N Am.* 2009;39(6):1173-1200.

⁴ Breitschwerdt EB, Hegarty BC, Maggi RG, Lantos PM, Aslett DM, Bradley JM. *Rickettsia rickettsii* transmission by a lone star tick, North Carolina. *Emerg Infect Dis.* 2011;17(5):873-875.

⁵ Data on File at Merial.

Merial is now part of
Boehringer Ingelheim.



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The vet's #1 choice for
their dogs and yours.¹



THE CHEW DOGS CHOOSE THAT KILLS FLEAS & TICKS.

NexGard®
(afoxolaner) Chewables



From the maker of

Heartgard®
(ivermectin/pyrantel) Plus

and

FRONTLINE®
Plus

FLEA HAVENS



UNDER SHRUBS



CARPET



WOODEN FLOORS



UNDER DECKS



FENCE LINES



URBAN WILDLIFE

TICK ZONES



TALL GRASS



TRAILS



LEAF LITTER



WOODED AREAS

THE LONE STAR TICK

Lone star ticks are widely distributed in the eastern United States, and the areas where they can be found are expanding. They are noted to be aggressive feeders and will actively seek out a host – such as your dog.

DISEASES TRANSMITTED³

BY THE LONE STAR TICK INCLUDE:

- Ehrlichiosis
- Rocky Mountain spotted fever (*Rickettsia rickettsii*)⁴
- Tularemia (*Francisella tularensis*)

“The lone star tick worries me. They’ve spread from Texas all the way to Michigan, Ontario and several southwestern counties in Maine – and they transmit a wider range of disease than *Ixodes scapularis*.”

— Dr. Michael Dryden, DVM, MS,
PhD, Kansas State University

LONE STAR COUNTRY



NexGard[®]
(afoxolaner) Chewables

**THE #1 CHOICE OF
VETS FOR THEIR
DOGS AND YOURS.¹**



**Recommended
by veterinarians.¹
Loved by dogs.⁵**

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**NexGard[®] (afoxolaner)
is delicious & powerful:**



It kills existing fleas fast



It kills adult fleas before
they can lay eggs



It kills ticks of veterinary importance:

- Black-legged (deer) ticks
- Lone star ticks
- American dog ticks
- Brown dog ticks



Safe for puppies as
young as 8 weeks old
weighing 4 pounds or more



It stays strong **ALL** month long



Can be given with or without food



It is easy to give and dogs love it⁵



It won't wash off



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PUPPY POWER

The fast-acting **NexGard®** (afoxolaner) formula is safe and effective for an entire month – and can be given to puppies.

- Safe for puppies as young as 8 weeks weighing 4 pounds or more

AND TO CELEBRATE...

the joyous act of adding a new puppy or grown dog to your family, check out **It's a Dog**. It's one of a kind, just like your new dog! Create a pet registry and learn how to provide great care for your dog.



NexGard®
(afoxolaner) Chewables

WHAT TO EXPECT

NexGard® (afoxolaner) is easy-to-give protection that goes to work killing fleas and ticks that prey on your dog.

- **NexGard** causes uncontrolled activity in the flea's central nervous system
- You might see fleas moving around on the surface of your dog's coat in a hyperactive state
- That means you're seeing **NexGard** working, and your flea problem dying!



STOP INFESTATIONS

NexGard will kill fleas on your dog, before fleas can lay eggs, all month long. The adult fleas you see on your dog are usually only 5% of the flea infestation in your environment. To prevent a flea infestation:



Give **NexGard** to your dog monthly.



Make sure all the pets in your house, even indoor cats, are treated with an appropriate flea and tick control product. Remember, **NexGard** is for Dogs only.

DOUBLE TROUBLE



Fleas remain a problem and according to a leading veterinary expert, ticks are a growing problem in many parts of the country.²

FLEAS CAN LEAD TO:

- Serious discomfort
- Anemia
- Flea allergy dermatitis
- Tapeworms
- Other diseases



TICKS CAN TRANSMIT

SERIOUS DISEASES, INCLUDING:

- Lyme disease
- Ehrlichiosis
- Tularemia
- Rocky Mountain spotted fever
- Babesiosis
- Anaplasmosis



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 (2.5 mg/kg). Afoxolaner has the chemical composition 1-Naphthalenecarboxamide, 4-[5-[3-chloro-5-(trifluoromethyl)-phenyl]-4, 5-dihydro-5-(trifluoromethyl)-3-isoxazolyl]-N-[2-oxo-2-(2,2,2-trifluoroethyl)amino]ethyl.

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*), Lone Star tick (*Amblyomma americanum*), and Brown dog tick (*Rhipicephalus sanguineus*) infestations in dogs and puppies 8 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 (2.5 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, redose 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 households 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		Oral active control	
	N ¹	% (n=415)	N ²	% (n=200)
Vomiting (with and without blood)	17	4.1	25	12.5
Dry/Flaky Skin	13	3.1	2	1.0
Diarrhea (with and without blood)	13	3.1	7	3.5
Lethargy	7	1.7	4	2.0
Anorexia	5	1.2	9	4.5

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/nexgard. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or online at <http://www.fda.gov/AnimalVeterinary/SafetyHealth>.

Mode of Action:

Afoxolaner is a member of the isoxazoline family, shown to bind at 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 hyperexcitation 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 >93% 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 (0-11 eggs and 1-17 eggs in the NexGard treated dogs, and 4-90 eggs and 0-118 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 of existing flea infestations.

In well-controlled laboratory studies, NexGard demonstrated >97% effectiveness against *Dermacentor variabilis*, >94% effectiveness against *Ixodes scapularis*, and >93% effectiveness against *Rhipicephalus sanguineus*, 48 hours post-infestation for 30 days. At 72 hours post-infestation, NexGard demonstrated >97% effectiveness against *Amblyomma americanum* 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, and 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 chewables: 11.3, 28.3, 68 or 136 mg afoxolaner. Each chewable size is available in color-coded packages of 1, 3 or 6 beef-flavored chewables.

NADA 141-406, Approved by FDA

Marketed by: Frontline Vet Labs[™], a Division of Meril, Inc.
Duluth, GA 30096-4640 USA

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