

NEXGARD- afoxolaner tablet, chewable **Frontline Vet Labs**

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. NexGard is indicated for the prevention of *Borrelia burgdorferi* infections as a direct result of killing *Ixodes scapularis* vector ticks.

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.

Keep NexGard in a secure location out of reach of dogs, cats, and other animals to prevent accidental ingestion or overdose.

Precautions:

Afoxolaner 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 dogs receiving isoxazoline class drugs, even in dogs without a history of seizures. Use with caution in dogs with a history of seizures or neurologic disorders.

The safe use of NexGard in breeding, pregnant or lactating dogs has not been evaluated.

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*	% (n=415)	N†	% (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

* Number of dogs in the afoxolaner treatment group with the identified abnormality.

† Number 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.

Post-Approval Experience (July 2018):

The following adverse events are based on post-approval adverse drug experience reporting. Not all adverse events are reported to FDA/CVM. It is not always possible to reliably estimate the adverse event frequency or establish a causal relationship to product exposure using these data.

The following adverse events reported for dogs are listed in decreasing order of reporting frequency for NexGard:

Vomiting, pruritus, lethargy, diarrhea (with and without blood), anorexia, seizure, hyperactivity/restlessness, panting, erythema, ataxia, dermatitis (including rash, papules), allergic reactions (including hives, swelling) and tremors.

Contact Information:

For a copy of the Safety Data Sheet (SDS) or to report suspected adverse drug events, contact Boehringer Ingelheim Animal Health USA Inc. at 1-888-637-4251 or www.nexgardfordogs.com.

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

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 \geq 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. In two separate, well-controlled laboratory studies, NexGard was effective at preventing *Borrelia burgdorferi* infections after dogs were infested with *Ixodes scapularis* vector ticks 28 days post-treatment.

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 chemistries, 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 5× 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.

Approved by FDA under NADA # 141-406

Marketed by:

Frontline Vet Labs™, a Division of Boehringer Ingelheim Animal Health USA Inc.
Duluth, GA 30096

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1050-4493-10
Rev. 06/2020

PRINCIPAL DISPLAY PANEL - 11.3 mg Tablet Carton

FOR DOGS 4-10.0 lbs

NexGard®
(afoxolaner) Chewables

Net Contents:

3 Chewables

Kills Fleas and Ticks

Soft Beef-Flavored
Chewables

- > Kills fleas before they can lay eggs
- > Prevents flea infestations
- > Lasts for the entire month

Each chewable contains
11.3 mg afoxolaner

Give once a month

FOR USE IN DOGS AND PUPPIES
8 WEEKS OF AGE AND OLDER

APPROVED BY FDA UNDER NADA # 141-406

CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DRUG TO USE BY OR ON THE ORDER OF A LICENSED VETERINARIAN. **HUMAN WARNING: 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.**

NexGard[®]

(afoxolaner) Chewables

FOR DOGS
4–10.0 lbs

3 Beef-Flavored
Chewables

Scan the code
to learn more
about NexGard



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NexGard[®] is a registered trademark and FRONTLINE VET LABS[®] is a trademark of the Boehringer Ingelheim Group.
Marketed by: Frontline Vet Labs[®], A Division of Boehringer Ingelheim Animal Health USA Inc., Duluth, GA 30096

Origin France.
FDA at 1-888-FDA-VETS or www.fda.gov/reportanimalae.
For additional information about adverse drug experience reporting for animal drugs, contact Frontline Vet Labs[®] at 1-888-637-4251 or www.nexgardfordogs.com.
Animal Health USA Inc. at 1-888-637-4251 or www.nexgardfordogs.com.
For complete product information, see package insert. Questions? Consult your veterinarian or to report suspected adverse events or for technical assistance, contact Boehringer Ingelheim

Keep NexGard in a secure location out of reach of dogs, cats, and other animals to prevent accidental ingestion or overdose.
Use with caution in dogs with a history of seizures or neurologic disorders.
For additional information about adverse drug experience reporting for animal drugs, contact Frontline Vet Labs[®] at 1-888-637-4251 or www.nexgardfordogs.com.
Animal Health USA Inc. at 1-888-637-4251 or www.nexgardfordogs.com.
For complete product information, see package insert. Questions? Consult your veterinarian or to report suspected adverse events or for technical assistance, contact Boehringer Ingelheim

Store at or below 30°C (86°F) with excursions permitted up to 40°C (104°F).
of 1.14 mg/lb (2.5 mg/kg).

Dosage and Administration: NexGard[®] is given orally once a month at the minimum dosage

NexGard[®] (afoxolaner) Chewables

FOR DOGS
4–10.0 lbs

Product 72405

NexGard[®]

(afoxolaner) Chewables

FOR DOGS
4–10.0 lbs

3 Beef-Flavored
Chewables



LOT:
SN:
EXP:

NexGard[®]

(afoxolaner) Chewables

FOR DOGS 4–10.0 lbs

Net Contents:
3 Chewables

Kills Fleas and Ticks

Soft Beef-Flavored
Chewables



- › Kills fleas before they can lay eggs
- › Prevents flea infestations
- › Lasts for the entire month



FOR DOGS
4–10.0 lbs
3 Beef-Flavored
Chewables

Gard[®]
Chewables

1030447709

1030447709

Each chewable contains
11.3 mg afoxolaner

Give once a month

FOR USE IN DOGS AND PUPPIES
8 WEEKS OF AGE AND OLDER

CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DRUG TO USE BY OR ON THE ORDER OF A LICENSED VETERINARIAN. HUMAN WARNING: 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.

Approved by FDA under NADA # 141-406

FRONTLINE VET LABS
A DIVISION OF SCIENTIFIC PRODUCTS ANIMAL HEALTH USA, INC.

Nex
(afoxolaner) (C)

PRINCIPAL DISPLAY PANEL - 28.3 mg Tablet Carton

FOR DOGS **10.1-24.0 lbs**

NexGard[®]
(afoxolaner) Chewables

Net Contents:

3 Chewables

Kills Fleas and Ticks

Soft Beef-Flavored
Chewables

- > Kills fleas before they can lay eggs
- > Prevents flea infestations
- > Lasts for the entire month

Each chewable contains
28.3 mg afoxolaner

Give once a month

FOR USE IN DOGS AND PUPPIES
8 WEEKS OF AGE AND OLDER

APPROVED BY FDA UNDER NADA # 141-406

CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DRUG TO USE BY OR ON THE ORDER OF A LICENSED VETERINARIAN. **HUMAN WARNING: 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.**

NexGard[®]

(afoxolaner) Chewables

FOR DOGS
10.1–24.0 lbs

3 Beef-Flavored
Chewables

Scan the code
to learn more
about NexGard



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FRONTLINE VET LABS[®] is a trademark of the Boehringer Ingelheim Group.

NexGard[®] is a registered trademark and
Boehringer Ingelheim Animal Health USA Inc., Duluth, GA 30096
Marketed by: Frontline Vet Labs[®], A Division of
Origin France.

FDA at 1-888-FDA-VETS or www.fda.gov/reportanimalae.
For additional information about adverse drug experience reporting for animal drugs, contact
Animal Health USA Inc. at 1-888-637-4251 or www.nexgardfordogs.com.
For complete product information, see package insert. Questions? Consult your veterinarian or
to report suspected adverse events or for technical assistance, contact Boehringer Ingelheim

Keep NexGard in a secure location out of reach of dogs, cats, and other animals to prevent
accidental ingestion or overdose.

Use with caution in dogs with a history of seizures or neurologic disorders.
reported in dogs receiving isoxazolone class drugs, even in dogs without a history of seizures.

Precautions: Afoxolaner is a member of the isoxazolone class. This class has been associated
with neurologic adverse reactions including tremors, ataxia, and seizures. Seizures have been
prevention of *Borrelia burgdorferi* infections as a direct result of killing ixodes scapularis vector ticks.

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.

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*).

Store at or below 30°C (86°F) with excursions permitted up to 40°C (104°F).
of 1.14 mg/lb (2.5 mg/kg).

Dosage and Administration: NexGard[®] is given orally once a month, at the minimum dosage

NexGard[®]

(afoxolaner) Chewables

FOR DOGS
10.1–24.0 lbs

Product 72407

NexGard[®]

(afoxolaner) Chewables

FOR DOGS
10.1–24.0 lbs

3 Beef-Flavored
Chewables

FOR DOGS 10.1–24.0 lbs

NexGard[®]

(afoxolaner) Chewables

Net Contents:
3 Chewables

Kills Fleas and Ticks

Soft Beef-Flavored
Chewables



- › Kills fleas before they can lay eggs
- › Prevents flea infestations
- › Lasts for the entire month



FOR DOGS
10.1–24.0 lbs

3 Beef-Flavored
Chewables

NexGard[®]
Chewables

1030447809

1030447809



LOT:
SN:
EXP:



PRINCIPAL DISPLAY PANEL - 68 mg Tablet Carton

FOR DOGS **24.1-60.0 lbs**

NexGard®
(afoxolaner) Chewables

Net Contents:

3 Chewables

Kills Fleas and Ticks

Soft Beef-Flavored
Chewables

- > Kills fleas before they can lay eggs
- > Prevents flea infestations
- > Lasts for the entire month

Each chewable contains
68 mg afoxolaner

Give once a month

FOR USE IN DOGS AND PUPPIES
8 WEEKS OF AGE AND OLDER

APPROVED BY FDA UNDER NADA # 141-406

CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DRUG TO USE BY OR ON THE ORDER OF A LICENSED VETERINARIAN. **HUMAN WARNING: 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.**

NexGard[®]

(afoxolaner) Chewables

FOR DOGS
24.1–60.0 lbs

3 Beef-Flavored
Chewables

Scan the code
to learn more
about NexGard



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Origin France.
FDA at 1-888-FDA-VETS or www.fda.gov/reportanimalae.
For additional information about adverse drug experience reporting for animal drugs, contact Animal Health USA Inc. at 1-888-637-4251 or www.nexgardfordogs.com.
For complete product information, see package insert. Questions? Consult your veterinarian or to report suspected adverse events or for technical assistance, contact Boehringer Ingelheim.
Keep NexGard in a secure location out of reach of dogs, cats, and other animals to prevent accidental ingestion or overdose.
Use with caution in dogs with a history of seizures or neurologic disorders.
Precarious: Afoxolaner 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 dogs receiving isoxazoline class drugs, even in dogs without a history of seizures. Prevention of Borrelia burgdorferi infections as a direct result of killing Ixodes scapularis vector ticks. (Rhipicephalus sanguineus) infestations in dogs and puppies 8 weeks of age and older. American Dog tick (Dermacentor variabilis), Lone Star tick (Amblyomma americanum), and Brown dog tick (Centrophe allodes felis), and the treatment and control of black-legged tick (Ixodes scapularis). NexGard kills adult fleas and is indicated for the treatment and prevention of flea infestations. Store at or below 30°C (86°F) with excursions permitted up to 40°C (104°F).
Dosage and Administration: NexGard[®] is given orally once a month, at the minimum dosage of 1.14 mg/lb (2.5 mg/kg).

NexGard[®]

(afoxolaner) Chewables

FOR DOGS
24.1–60.0 lbs

Product 72409

NexGard[®]

(afoxolaner) Chewables

FOR DOGS
24.1–60.0 lbs

3 Beef-Flavored
Chewables

FOR DOGS 24.1–60.0 lbs

Net Contents:
3 Chewables

NexGard[®]

(afoxolaner) Chewables

Kills Fleas and Ticks

Soft Beef-Flavored
Chewables



- › Kills fleas before they can lay eggs
- › Prevents flea infestations
- › Lasts for the entire month



FOR DOGS
24.1–60.0 lbs

3 Beef-Flavored
Chewables

Gard[®]
Chewables

1030447909

1030447909



LOT:
SN:
EXP:



PRINCIPAL DISPLAY PANEL - 136 mg Tablet Carton

FOR DOGS **60.1-121.0 lbs**

NexGard®
(afoxolaner) Chewables

Net Contents:

3 Chewables

Kills Fleas and Ticks

Soft Beef-Flavored
Chewables

- > Kills fleas before they can lay eggs
- > Prevents flea infestations
- > Lasts for the entire month

Each chewable contains
136 mg afoxolaner

Give once a month

FOR USE IN DOGS AND PUPPIES
8 WEEKS OF AGE AND OLDER

APPROVED BY FDA UNDER NADA # 141-406

CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DRUG TO USE BY OR ON THE ORDER OF A LICENSED VETERINARIAN. **HUMAN WARNING: 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.**

NexGard[®]

(afoxolaner) Chewables

FOR DOGS
60.1–121.0 lbs

3 Beef-Flavored
Chewables

Scan the code
to learn more
about NexGard



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Origin France.

FDA at 1-888-FDA-VETS or www.fda.gov/reportanimalae.
For additional information about adverse drug experience reporting for animal drugs, contact
Animal Health USA Inc. at 1-888-637-4251 or www.nexgardfordogs.com.
For complete product information, see package insert. Questions? Consult your veterinarian or
report suspected adverse events or for technical assistance, contact Boehringer Ingelheim

Keep NexGard in a secure location out of reach of dogs, cats, and other animals to prevent
accidental ingestion or overdose.

Use with caution in dogs with a history of seizures or neurologic disorders.
Use with caution in dogs receiving isoxazolone class drugs, even in dogs without a history of seizures.

Precautions: Afoxolaner is a member of the isoxazolone class. This class has been associated
with neurologic adverse reactions including tremors, ataxia, and seizures. Seizures have been
reported in dogs receiving isoxazolone class drugs, even in dogs without a history of seizures.

prevention of *Borrelia burgdorferi* infections as a direct result of killing ixodes scapularis vector ticks.
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.

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*).

Store at or below 30°C (86°F) with excursions permitted up to 40°C (104°F).
of 114 mg/lb (2.5 mg/kg).

Dosage and Administration: NexGard[®] is given orally once a month, at the minimum dosage

NexGard[®]

(afoxolaner) Chewables

FOR DOGS
60.1–121.0 lbs

Product 72411

NexGard[®]

(afoxolaner) Chewables

FOR DOGS
60.1–121.0 lbs

3 Beef-Flavored
Chewables

FOR DOGS **60.1–121.0 lbs**

Net Contents:
3 Chewables

NexGard[®]

(afoxolaner) Chewables

Kills Fleas and Ticks

Soft Beef-Flavored
Chewables



- › Kills fleas before they can lay eggs
- › Prevents flea infestations
- › Lasts for the entire month



FOR DOGS
60.1–121.0 lbs

3 Beef-Flavored
Chewables

Gard[®]
Chewables

1030448009

1030448009



LOT:
SN:
EXP:

Each chewable contains
136 mg afoxolaner

Give once a month

FOR USE IN DOGS AND PUPPIES
8 WEEKS OF AGE AND OLDER

CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DRUG TO USE BY OR ON THE ORDER OF A LICENSED VETERINARIAN. HUMAN WARNING: 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.

Approved by FDA under NADA # 141-406

FRONTLINE VET LABS
A DIVISION OF SCIENTIFIC PRODUCTS COMPANY, LLC, USA, INC.

Nex
(afoxolaner)

NEXGARD

afoxolaner tablet, chewable

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:59415-2405
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
afoxolaner (UNII: 02L07H6D0U) (afoxolaner - UNII:02L07H6D0U)	afoxolaner	11.3 mg

Product Characteristics

Color	RED (mottled red to reddish-brown)	Score	no score
Shape	ROUND	Size	9mm
Flavor	MEAT (Beef)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59415-2405-1	1 in 1 CARTON		
1		3 in 1 BLISTER PACK		
2	NDC:59415-2405-2	1 in 1 CARTON		
2		6 in 1 BLISTER PACK		
3	NDC:59415-2405-3	1 in 1 CARTON		
3		1 in 1 BLISTER PACK		
4	NDC:59415-2405-4	1 in 1 CARTON		
4		1 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA141406	05/08/2020	

NEXGARD

afoxolaner tablet, chewable

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:59415-2407
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
afoxolaner (UNII: 02L07H6D0U) (afoxolaner - UNII:02L07H6D0U)	afoxolaner	28.3 mg

Product Characteristics

Color	RED (mottled red to reddish-brown)	Score	no score
Shape	RECTANGLE	Size	12mm
Flavor	MEAT (Beef)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59415-2407-1	1 in 1 CARTON		
1		3 in 1 BLISTER PACK		
2	NDC:59415-2407-2	1 in 1 CARTON		
2		6 in 1 BLISTER PACK		
3	NDC:59415-2407-3	1 in 1 CARTON		
3		1 in 1 BLISTER PACK		
4	NDC:59415-2407-4	1 in 1 CARTON		
4		1 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA141406	05/08/2020	09/30/2025

NEXGARD

afoxolaner tablet, chewable

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:59415-2409
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
afoxolaner (UNII: 02L07H6D0U) (afoxolaner - UNII:02L07H6D0U)	afoxolaner	68 mg

Product Characteristics

Color	RED (mottled red to reddish-brown)	Score	no score
Shape	RECTANGLE	Size	20mm
Flavor	MEAT (Beef)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59415-2409-1	1 in 1 CARTON		
1		3 in 1 BLISTER PACK		
2	NDC:59415-2409-2	1 in 1 CARTON		
2		6 in 1 BLISTER PACK		
3	NDC:59415-2409-3	1 in 1 CARTON		
3		1 in 1 BLISTER PACK		
4	NDC:59415-2409-4	1 in 1 CARTON		
4		1 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA141406	05/08/2020	09/30/2025

NEXGARD

afoxolaner tablet, chewable

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:59415-2411
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
afoxolaner (UNII: 02L07H6D0U) (afoxolaner - UNII:02L07H6D0U)	afoxolaner	136 mg

Product Characteristics

Color	RED (mottled red to reddish-brown)	Score	no score
Shape	RECTANGLE	Size	26mm

Flavor	MEAT (Beef)		Imprint Code	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59415-2411-1	1 in 1 CARTON		
1		3 in 1 BLISTER PACK		
2	NDC:59415-2411-2	1 in 1 CARTON		
2		6 in 1 BLISTER PACK		
3	NDC:59415-2411-3	1 in 1 CARTON		
3		1 in 1 BLISTER PACK		
4	NDC:59415-2411-4	1 in 1 CARTON		
4		1 in 1 BLISTER PACK		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
NADA	NADA141406		05/08/2020	09/30/2025

Labeler - Frontline Vet Labs (078674099)

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Frontline Vet Labs