

Product Name: NexGard Spectra Chewables for Dogs 30.1 - 60 kg
 APVMA Approval No: 81055/114915



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Label Name:	NexGard Spectra Chewables for Dogs 30.1 - 60 kg
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Signal Headings:	<p>CAUTION KEEP OUT OF REACH OF CHILDREN FOR ANIMAL TREATMENT ONLY READ SAFETY DIRECTIONS</p>

Constituent Statements:	Each chewable contains 150 mg Afoxolaner and 30 mg Milbemycin Oxime

Claims:	<ul style="list-style-type: none"> • Rapidly kills fleas • Treats and controls ticks • Treats and controls mange and mites • Prevents heartworm disease • Treats and controls roundworms, hookworms and whipworms • Controls flea allergy dermatitis • Prevents flea tapeworm infestations • Monthly treatment • Tasty chew <p>For 30.1 - 60 kg dogs</p> <p>Indications: For the treatment and prevention of flea infestations, control of ticks and mites, prevention of heartworm, and treatment and control of intestinal worms in dogs and puppies from 8 weeks of age.</p> <p>NexGard Spectra rapidly kills adult fleas and is indicated for the treatment and prevention of flea (<i>Ctenocephalides</i> spp.) infestations, for the control of newly acquired adult fleas and for the control of flea allergy dermatitis. Following administration, fleas are killed within 6-8 hours. Rapid onset of action kills newly acquired fleas before they can lay eggs. Fleas can transmit flea tapeworm (<i>Dipylidium caninum</i>). Effective flea control with NexGard Spectra prevents flea tapeworm infestation in dogs.</p>
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NexGard Spectra treats and controls Paralysis ticks (*Ixodes holocyclus*), Brown Dog ticks (*Rhipicephalus sanguineus*) and Bush ticks (*Haemaphysalis longicornis*) for one month. NexGard Spectra provides effective control of pre-existing Paralysis tick infestations within 24 hours. *Ixodes holocyclus* ticks do not occur in Western Australia. In tick season, daily searching for, and removal of, any ticks found is recommended.

NexGard Spectra treats and controls demodectic mange caused by *Demodex* spp., sarcoptic mange caused by *Sarcoptes scabiei* and ear mite (*Otodectes cynotis*) infestations.

NexGard Spectra prevents heartworm disease caused by *Dirofilaria immitis* and treats and controls roundworms (*Toxocara canis* and *Toxascaris leonina*), hookworms (*Ancylostoma caninum* and *A. ceylanicum*) and whipworms (*Trichuris vulpis*). Consult a veterinarian if worm problems persist. Monthly administration is recommended.

Net Contents:

1 Chewable / 3 Chewables / 6 Chewables
Illegal to sell chewables separately.

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Directions for Use:

Restrains:

Contraindications:

Precautions:

The safe use of NexGard Spectra chewables in breeding males and females has not been evaluated.

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Side Effects:

Dosage and Administration:

The recommended dosage for 30.1 - 60 kg dogs is one 8 g chewable (150 mg afoxolaner and 30 mg milbemycin oxime/chewable) to deliver a minimum of 2.5 mg of afoxolaner

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per kg bodyweight and 0.5 mg of milbemycin oxime per kg of bodyweight. Offer the chewable(s) appropriate for your dog's weight at monthly intervals. Remove only one chewable at a time from the foil-backed blister card. NexGard Spectra may be broken into pieces and fed to dogs who normally swallow treats whole. NexGard Spectra is a soft, highly palatable chewable and is readily consumed by dogs when offered as a treat. Alternatively, NexGard Spectra may be added intact to a small amount of dog food.

Care should be taken that the dog consumes the complete dose, and treated dogs should be observed for a few minutes to ensure that part of the dose is not lost or rejected. If it is suspected that any of the dose has been lost, treat again with another full dose. If a dose is missed, administer the NexGard Spectra chewable(s) appropriate for your dog's weight and resume a monthly dosing regimen.

The recommended minimum monthly dosage is 2.5 mg afoxolaner per kg bodyweight and 0.5 mg milbemycin oxime per kg:

Dog Size	Chewable size (g)	Dog weight (kg)	Afoxolaner (mg/chew)	Milbemycin oxime (mg/chew)
Very small	0.5	2 - 3.5	9.4	1.9
Small	1	3.6 - 7.5	18.8	3.8
Medium	2	7.6 - 15.0	37.5	7.5
Large	4	15.1 - 30.0	75.0	15.0
Very Large	8	30.1 - 60.0	150.0	30.0

For dogs over 60kg, administer the appropriate combination of chewables.
For optimal performance, treat your dog on or about the same day each month.

General Directions:

Safety to Dogs
NexGard Spectra was shown to be safe in various breeds of dogs (including Collie breeds) and in puppies 8 weeks and older.

Afoxolaner is part of the isoxazoline family of chemicals. Adverse reactions to this family of chemicals are rarely observed but may include vomiting, diarrhoea, lethargy, inappetence, itching and very rarely, seizures. Most adverse reactions are self-limiting and of short duration. If you have any concerns, please speak to your veterinarian.

GENERAL INSTRUCTIONS

As NexGard Spectra is an oral treatment, there are no restrictions on swimming, bathing and shampooing before or after administration.

Flea Treatment and Prevention
NexGard Spectra demonstrated rapid control of fleas for a full month. Because fleas are killed rapidly, NexGard Spectra controls flea allergy dermatitis.

Treatment with NexGard Spectra may begin at any time of the year. Dogs become infested with fleas that originate from environmental infestation sites in the home or outdoors. Treatment and prevention of flea infestations is achieved by killing fleas on the dog before they can lay eggs and replenish an environmental infestation. If a severe environmental infestation exists, fleas can continue to emerge into the surroundings for weeks to months, because of the continuing development of flea eggs, larvae and pupae already present at the time of treatment. It may therefore take more than one monthly treatment to achieve control of moderate to heavy pre-existing flea infestations.

In areas where fleas are common year-round, monthly treatment with NexGard Spectra should continue throughout the year without interruption.

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

Tick Control
For the most effective control of Paralysis ticks (*Ixodes holocyclus*) and to minimise the risk of tick paralysis, NexGard Spectra should be used in conjunction with daily searching and removal of ticks. Treatment with NexGard Spectra alone will not entirely remove the risk of tick paralysis. Speak with your veterinarian for advice on tick searching and removal techniques.

NexGard Spectra demonstrated >95% efficacy for a full month against Paralysis ticks, Brown Dog ticks and Bush ticks. In Australian studies, Paralysis ticks were killed (>95% efficacy) within 48 hours. Brown Dog ticks and Bush ticks were killed (>95% efficacy)

within 48 hours. Treatment with NexGard Spectra may begin at any time of the year. Dogs become infested with ticks that originate from sites which are primarily outdoors. In areas where ticks are common year-round, monthly treatment with NexGard Spectra should continue throughout the year without interruption.

Treatment and Control of Mites

Monthly treatment with NexGard Spectra effectively treats and controls generalised demodectic mange caused by Demodex mites). Treated dogs experience a marked reduction of skin lesions and significant hair-regrowth. Monthly treatment should be continued until the absence of mites is confirmed by two consecutive monthly skin scrapings.

NexGard Spectra effectively treats and controls sarcoptic mange (*Sarcoptes scabiei*) and improves clinical signs significantly. Two consecutive monthly treatments are recommended.

A single dose of NexGard Spectra is highly effective against ear mite (*Otodectes cynotis*) infestations in dogs. If ear irritation persists, consult a veterinarian.

Heartworm Disease Prevention

NexGard Spectra should be administered monthly to prevent heartworm disease.

Treatment with NexGard Spectra should continue throughout the year without interruption. When replacing another heartworm preventative product, the first dose of NexGard Spectra should be administered within one month of the last dose of the previous monthly medication.

Consult your veterinarian before starting a heartworm prevention program. Heartworms can have serious effects on the health of dogs. The use of NexGard Spectra in heartworm positive dogs has not been evaluated.

Gastrointestinal Worms

Roundworms, hookworms and whipworms cause illness in dogs. Regular treatment with NexGard Spectra provides effective treatment and control of roundworms (*T. canis* and *T. leonina*), hookworms (*A. caninum* and *A. ceylanicum*) and whipworms (*T. vulpis*).

The flea tapeworm (*D. caninum*) is transmitted by fleas. Dogs become infested by ingesting adult fleas carrying the tapeworm larvae. Effective flea control with NexGard Spectra prevents infestation.

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Withholding Periods:	

Trade Advice:	

Safety Directions:	Do not swallow. Do not open inner pouch until ready for use. Wash hands after use

First Aid Instructions:	If poisoning occurs contact a doctor or Poisons Information Centre. Phone Australia 131126. If in eyes, hold eyes open, flood with water for at least 15 minutes and see a doctor.

First Aid Warnings:		

Additional User Safety:	Accidental ingestion of afoxolaner can be harmful to children. To avoid accidental ingestion administer the chewable to the dog immediately after removal from the package. Keep out of reach of children. Additional information is in the Safety Data Sheet.	

Environmental Statements:		

Disposal:	Dispose of empty pack by wrapping in paper and placing in garbage.	

Storage:	Store below 30°C (Room temperature). Protect from light.	