



Product Name: NEXGARD CHEWABLES FOR DOGS 2-4 KG  
APVMA Approval No: 67942/142104

Label Name:	NEXGARD CHEWABLES FOR DOGS 2-4 KG
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Signal Headings:	CAUTION KEEP OUT OF REACH OF CHILDREN FOR ANIMAL TREATMENT ONLY READ SAFETY DIRECTIONS
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Constituent Statements:	Each chewable contains 11.3 mg afoxolaner
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Claims:	<p>For the treatment and prevention of flea infestations and control of ticks, mites and biting lice on dogs and puppies.</p> <ul style="list-style-type: none"><li>• Rapidly kills fleas</li><li>• Treats and controls ticks</li><li>• Treats and controls mange and mites</li><li>• Treats and controls biting lice</li><li>• Prevents flea tapeworm infestations</li><li>• Controls flea allergy dermatitis</li><li>• Effective for one month</li><li>• Tasty chew</li></ul> <p>For 2 – 4 kg dogs</p> <p>NexGard contains afoxolaner, a member of the isoxazoline family of chemicals.</p> <p>NexGard rapidly kills adult fleas and is indicated for the treatment and prevention of flea (<i>Ctenocephalides</i> spp.) infestations for 5 weeks (35 days), 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 prevents flea tapeworm infestation in dogs.</p> <p>NexGard treats and controls paralysis ticks (<i>Ixodes holocyclus</i>), brown dog ticks (<i>Rhipicephalus sanguineus</i>) and bush ticks (<i>Haemaphysalis longicornis</i>) for 5 weeks (35 days). NexGard provides effective control of pre-existing paralysis tick infestations within 24 hours. <i>Ixodes holocyclus</i> ticks do not occur in Western Australia. In tick season, daily searching for, and removal of, any ticks found is recommended.</p> <p>NexGard treats and controls demodectic mange caused by <i>Demodex</i> spp., sarcoptic mange caused by <i>Sarcoptes scabiei</i> and ear mite (<i>Otodectes cynotis</i>) infestations.</p>
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	<p>NexGard treats and controls biting lice (<i>Trichodectes canis</i>).</p> <p>Monthly administration is recommended.</p> <p>For use in puppies from 8 weeks of age.</p> <p>NexGard can be used in breeding, pregnant and lactating females.</p>
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Net Contents:	<p>1 chewable 3 chewables 6 chewables</p> <p>Illegal to sell chewables separately.</p>
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Directions for Use:	
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Restrictions:	
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Contraindications:	Not to be used in dogs less than 8 weeks of age.
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Precautions:	The safe use of NexGard chewables in breeding males has not been evaluated.
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Side Effects:	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.
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Dosage and Administration:	<p>The recommended dosage for 2 - 4 kg dogs is one 0.5 g chewable (11.3 mg afoxolaner / chewable) or 2.5 mg of afoxolaner per kg bodyweight. Offer the chewable(s) appropriate for your dog's weight at monthly intervals.</p> <p>Remove only one chewable at a time from the foil-backed blister card. NexGard is a soft, highly palatable chewable and is readily consumed by dogs when offered as a treat. NexGard can also be given with a small amount of food or directly into the mouth.</p> <p>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 chewable(s) appropriate for your dog's weight and resume a monthly dosing regimen.</p> <p>The recommended minimum monthly dosage is 2.5 mg afoxolaner per kg bodyweight:</p> <p>[Insert table]</p> <p>For dogs over 50 kg, administer the appropriate combination of chewables.</p> <p>For optimal parasite control, treat your dog on or about the same day each month, regardless of how many days in the month.</p> <p>This section contains file attachment.</p>
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General Directions:

Safety to Dogs

NexGard was shown to be safe in various breeds of dogs and in puppies 8 weeks and older.

NexGard has also been shown to be safe in dogs with the ABCB1 (formerly known as MDR-1) gene mutation, such as ivermectin-sensitive Collie breeds.

NexGard may be administered in conjunction with gastrointestinal worm or heartworm treatments administered according to label directions.

GENERAL INSTRUCTIONS

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

Flea and Lice Control

Treatment and prevention of fleas: NexGard demonstrated rapid control of fleas for 5 weeks (35 days), ensuring protection for a full month. Because fleas are killed rapidly, NexGard controls flea allergy dermatitis.

Treatment with NexGard 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.

Under conditions of moderate to heavy challenge it may 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 should continue throughout the year without interruption.

Treatment and control of biting lice: NexGard treats and controls biting lice (*Trichodectes canis*). A single dose of afoxolaner demonstrated 100% efficacy against biting lice for 30 days.

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

Tick Control

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

NexGard demonstrated >95% efficacy for 5 weeks (35 days) against paralysis ticks, brown dog ticks and bush ticks, ensuring protection for a full month. In Australian studies, paralysis ticks and brown dog ticks were killed (>95% efficacy) within 48 hours. Bush ticks were killed (>95% efficacy) within 72 hours.

Treatment with NexGard 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 should continue throughout the year without interruption.

Treatment and Control of Mites

Monthly treatment with NexGard 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 effectively treats and controls sarcoptic mange (*Sarcoptes scabiei*) for a month and improves clinical signs significantly. Two consecutive monthly treatments are recommended.

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

#### Prevention of Flea Tapeworm Infestation

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 prevents new infestations. To treat an existing infestation, a product registered to treat flea tapeworm should be administered.

NOT TO BE USED FOR ANY PURPOSE, OR IN ANY MANNER, CONTRARY TO THIS LABEL UNLESS AUTHORISED UNDER APPROPRIATE LEGISLATION

Withholding Periods:

Trade Advice:

Safety Directions:

Do not swallow. Wash hands after use.

First Aid Instructions:

If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 13 11 26.

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 (SDS).

Environmental Statements:

Disposal:

Dispose of container by wrapping with paper and putting in garbage.

Storage:

Store below 30 °C (room temperature).

**NEXGARD CHEWABLES FOR DOGS DOSAGE TABLE**

<b>Dog weight (kg)</b>	<b>Chewable size (g)</b>	<b>Afoxolaner (mg/chew)</b>
2 - 4	0.5	11.3
4.1 - 10	1.25	28.3
10.1 - 25	3	68.0
25.1 - 50	6	136.0