



Australian Pesticides &
Veterinary Medicines Authority

Product Name: Nexgard Spectra Spot-On for Cats 2.5 - 7.5 kg
APVMA Approval No: 90860/145070

Label Name:	Nexgard Spectra Spot-On for Cats 2.5 - 7.5 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:	83 g/L PRAZIQUANTEL 12 g/L ESAFOXOLANER 4 g/L EPRINOMECTIN
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Claims:	<p>NEXGARD SPECTRA contains praziquantel, a synthetic isoquinoline-pyrazine derivative, esafoxolaner, a member of the isoxazoline family of chemicals, and eprinomectin, a member of the macrocyclic lactone family.</p> <ul style="list-style-type: none">• Controls fleas• Controls new infestations of paralysis ticks with monthly treatments• Treats and controls bush ticks• Controls brown dog ticks• Treats and controls mange and ear mites• Prevents heartworm disease• Treats and controls roundworms, hookworms, lungworm, and tapeworms• Controls flea allergy dermatitis• Monthly topical treatment <p>For cats 2.5 - 7.5 kg</p> <p>INDICATIONS</p> <p>For the treatment and prevention of flea infestations, control of ticks and mites, prevention of heartworm disease, and treatment and control of intestinal worms in cats and kittens from 8 weeks of age.</p> <p>NEXGARD SPECTRA controls adult fleas (<i>Ctenocephalides felis</i>) and treats and prevents flea infestations for at least 5 weeks. NEXGARD SPECTRA kills (>95% efficacy) newly acquired adult fleas before they can lay eggs, and therefore prevents environmental flea contamination by preventing egg laying for at least one month.</p> <p>NEXGARD SPECTRA controls flea allergy dermatitis (FAD).</p> <p>NEXGARD SPECTRA controls new infestations of paralysis ticks (<i>Ixodes holocyclus</i>) with monthly treatments.</p>
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NEXGARD SPECTRA controls new infestations of paralysis ticks acquired from 24 hours after the first treatment.

When administered at monthly intervals, NEXGARD SPECTRA continuously controls new infestations of paralysis ticks for a full month. NOTE: As NEXGARD SPECTRA may not kill all ticks attached when cats are first treated, any ticks present at the time of first treatment should be removed.

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 bush ticks (*Haemaphysalis longicornis*) for one month. Bush ticks were killed (>95% efficacy) within 48 hours after treatment.

NEXGARD SPECTRA controls brown dog ticks (*Rhipicephalus sanguineus*) for 5 weeks. Brown dog ticks were killed (>95% efficacy) within 72 hours after treatment and within 48 hours of weekly infestations for 5 weeks.

NEXGARD SPECTRA treats and controls ear mite (*Otodectes cynotis*) infestations and notoedric mange caused by *Notoedres cati*.

NEXGARD SPECTRA treats and controls gastrointestinal roundworms (*Toxocara cati* [L3, L4 and adult], *Toxascaris leonina* [adult]), and hookworms (*Ancylostoma tubaeforme* [L4 and adult], *Ancylostoma ceylanicum* [L4 and adult]), and *Ancylostoma braziliense* [adult]).

NEXGARD SPECTRA treats and controls *Dipylidium caninum* and *Taenia taeniaeformis* tapeworms.

NEXGARD SPECTRA prevents heartworm disease caused by *Dirofilaria immitis*.

NEXGARD SPECTRA treats and controls lungworm (*Aelurostrongylus abstrusus*). A single dose of NEXGARD SPECTRA is effective against L3, L4 and adult *A. abstrusus*. Two consecutive, monthly doses are effective against all stages (L3, L4, immature and adult) of *A. abstrusus*.

Consult a veterinarian if worm problems persist.
Monthly application is recommended.

Net Contents:

1 x 0.9 mL
2 x 0.9 mL
3 x 0.9 mL
4 x 0.9 mL
6 x 0.9 mL
9 x 0.9 mL
12 x 0.9 mL
15 x 0.9 mL

It is illegal to sell individual applicators separately.

Directions for Use:

Restraints:

Contraindications:

Do not use in cases of hypersensitivity to the active constituents or to any of the excipients.

Not recommended for use on kittens under 8 weeks of age or weighing less than 0.8 kg.

Precautions:	Avoid contact with the cat's eyes. If accidental eye contact occurs, flush the eyes immediately with water. If eye irritation persists, seek veterinary advice.
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Side Effects:	<p>If licking occurs shortly after application, a brief period of hypersalivation may occur.</p> <p>Hypersalivation, diarrhoea, transient skin reactions at the application site (alopecia, pruritus), anorexia, lethargy, and emesis were uncommonly observed in clinical trials shortly after administration.</p> <p>These were mostly mild reactions of short duration and self-limiting.</p>
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Dosage and Administration:	<p>For topical application onto the skin (spot-on) only. Do not administer orally or via any other route.</p> <p>Do not open applicator blister pack until ready to use.</p> <p>Select the appropriate applicator size for the weight of the cat as follows: Cat weight (kg) Treatment volume (mL)</p> <table><tr><td>0.8 to 2.4 kg</td><td>0.3 mL applicator</td></tr><tr><td>2.5 to 7.5 kg</td><td>0.9 mL applicator</td></tr></table> <p>For cats over 7.5 kg use the appropriate combination of applicators.</p> <p>The recommended minimum doses are 1.44 mg/kg esafoxolaner, 0.5 mg/kg eprinomectin, and 10 mg/kg praziquantel.</p> <p>Method of administration:</p> <ol style="list-style-type: none">1. Use scissors to cut the blister along the dotted line, then pull the lid away.2. Remove the applicator from the package and hold it upright.3. Pull back the plunger slightly, twist and pull off the cap.4. Part the hair on the midline of the neck, between the base of the skull and the shoulder blades until the skin is visible.5. Place the tip of the applicator on the skin and apply the entire contents directly onto the skin in one spot.6. Opened applicators should be disposed of immediately. <p>The entire contents of the applicator should be applied to dry skin in an area where the cat cannot lick it off: e.g. on the back of the neck. In long-haired breeds, special attention should be paid to apply the product onto the skin, and not on the hair, to ensure optimal efficacy.</p> <p>For use on kittens from 8 weeks of age.</p> <p>Monthly application is recommended. For optimal performance treat your cat on or about the same day each month.</p>	0.8 to 2.4 kg	0.3 mL applicator	2.5 to 7.5 kg	0.9 mL applicator
0.8 to 2.4 kg	0.3 mL applicator				
2.5 to 7.5 kg	0.9 mL applicator				

General Directions:	<p>SAFETY TO CATS</p> <p>NEXGARD SPECTRA was shown to be safe in various breeds of cats and kittens 8 weeks of age and older, and in breeding, pregnant or lactating queens.</p> <p>Esafoxolaner 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.</p> <p>GENERAL INSTRUCTIONS</p>
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Efficacy of the product after shampooing or wetting has not been assessed.

Flea Treatment and Prevention

NEXGARD SPECTRA demonstrated treatment and control of fleas for a full month and controls flea allergy dermatitis.

Treatment with NEXGARD SPECTRA may begin at any time of the year. Cats 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 (>95% efficacy) on the cat 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. If more rapid resolution of heavy environmental infestations is required, additional environmental control using a registered premises treatment may be implemented. 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.

Treatment with NEXGARD SPECTRA may begin at any time of the year. Cats 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.

When administering NEXGARD SPECTRA for the first time, it should be applied at least 24 hours prior to any potential tick exposure.

In clinical studies, newly acquired paralysis ticks (*Ixodes holocyclus*) were killed (>95% efficacy) within 72 hours of weekly infestations for 5 weeks. Monthly re-treatment is recommended for continuous control of new infestations.

NEXGARD SPECTRA demonstrated >95% efficacy against bush ticks (*Haemaphysalis longicornis*) for one month. Bush ticks were killed (>95% efficacy) within 48 hours after treatment.

NEXGARD SPECTRA demonstrated >95% efficacy against brown dog ticks (*Rhipicephalus sanguineus*) for 5 weeks. Brown dog ticks were killed (>95% efficacy) within 72 hours after treatment and within 48 hours of weekly infestations for 5 weeks.

Treatment and Control of Mites

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

NEXGARD SPECTRA effectively treats and controls notoedric mange (*Notoedres cati*).

Heartworm Disease Prevention

NEXGARD SPECTRA should be applied monthly to prevent heartworm disease. Treatment with NEXGARD SPECTRA should continue throughout the year without interruption.

Prevention of heartworm disease (*D. immitis* larvae) should start within 1 month after the first expected exposure to mosquitoes. When replacing another heartworm preventative

product, the first dose of NEXGARD SPECTRA should be applied 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 cats. Although NEXGARD SPECTRA may be safely administered to cats infected with adult heartworms, no therapeutic effect against adult *Dirofilaria immitis* has been established. It is therefore recommended that all cats 6 months of age or more, living in areas endemic for heartworm, should be tested for existing adult heartworm infestation before starting on heartworm prevention.

Gastrointestinal Worms

Roundworms and hookworms cause illness in cats. Regular treatment with NEXGARD SPECTRA provides effective treatment and control of roundworms (*T. cati* and *T. leonina*) and hookworms (*A. tubaeforme*, *A. braziliense*, and *A. ceylanicum*).

Tapeworm

NEXGARD SPECTRA treats and controls *Dipylidium caninum* and *Taenia taeniaeformis* tapeworms. These tapeworm infestations may reoccur unless control of intermediate hosts such as fleas, mice etc. is undertaken. The flea tapeworm (*D. caninum*) is transmitted by fleas. Cats become infested by ingesting adult fleas carrying the tapeworm larvae. Effective flea control with NEXGARD SPECTRA prevents infestation by ongoing control of the intermediate host with year-round monthly application.

Lungworms

Feline lungworm (*Aelurostrongylus abstrusus*) can lead to severe, life-threatening respiratory disease in cats. NEXGARD SPECTRA treats existing *Aelurostrongylus abstrusus* infestations in cats and repeated monthly applications will prevent and control any subsequent infestations.

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:

Will irritate the eyes. Avoid contact with eyes and skin. If product in eyes, wash it out immediately with water. If skin contact occurs, wash the affected area immediately with clean water. Wash hands after use.

First Aid Instructions:

If poisoning occurs contact a doctor or Poisons Information Centre. Phone Australia 131126.

First Aid Warnings:

Additional User Safety:

Rehandling statement:

Do not contact or allow children to contact the application site until it is dry. Handling of treated animals should be limited during this period. On the day of treatment, treated animals should not be permitted to sleep with their owner, especially children.

Additional information is listed in the Safety Data Sheet (SDS).

Environmental Statements:	
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Disposal:	Dispose of container by wrapping in paper and placing in garbage.
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Storage:	Store below 30°C (Room Temperature). Store the applicator in the blister package to protect from light. Keep the unused applicator in the intact blister package.
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