

AcuGuard® (spinosad) Chewable Tablets



ACUGUARD®-Cats (spinosad)

Chewable Tablets

For information on dogs, see reverse side.

Caution: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

Description:

ACUGUARD (spinosad) is available in four sizes of chewable flavored tablets for oral administration to cats and kittens according to their weight. Each chewable flavored tablet is formulated to provide a minimum spinosad dosage of 22.5 mg/lb (50 mg/kg). Spinosad is a member of the spinosyns class of insecticides, which are non-antibacterial tetracyclic macrolides. Spinosad contains two major factors, spinosyn A and spinosyn D, derived from the naturally occurring bacterium, *Saccharopolyspora spinosa*. Spinosyn A and spinosyn D have the chemical compositions 2-[(6-deoxy-2,3,4-tri-O-methyl- α -L-mannopyranosyl)oxy]-13-[[5-(dimethylamino)tetrahydro-6-methyl-2H-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-14-methyl-1H-as-indaceno[3,2-d]oxacyclododecin-7,15-dione and 2-[(6-deoxy-2,3,4-tri-O-methyl- α -L-mannopyranosyl)oxy]-13-[[5-(dimethylamino)tetrahydro-6-methyl-2H-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-4,14-dimethyl-1H-as-indaceno[3,2-d]oxacyclododecin-7,15-dione, respectively.

Indications:

ACUGUARD kills fleas and is indicated for the prevention and treatment of flea infestations (*Ctenocephalides felis*), for one month, on cats and kittens 14 weeks of age and older and two pounds of body weight or greater.

Dosage and Administration:

ACUGUARD is given orally once a month, at the minimum dosage of 22.5 mg/lb (50 mg/kg).

Do not use the dosing schedule below when administering ACUGUARD to dogs, as it can result in an overdose.

Dosage Schedule:

Body Weight	Spinosad Per Tablet (mg)	Tablets Administered
2 to 4 lbs	90	One
4.1 to 6 lbs	140	One
6.1 to 12 lbs	270	One
12.1 to 24* lbs	560	One

*Cats over 24 lbs should be administered the appropriate combination of tablets.

Administer ACUGUARD with food for maximum effectiveness.

ACUGUARD is a chewable tablet that can be consumed by cats when offered by the owner just prior to or after feeding. Alternatively, ACUGUARD may be offered in food or administered like other tablet medications. ACUGUARD should be administered at monthly intervals.

If vomiting occurs within an hour of administration, redose with another full dose. If a dose is missed, administer ACUGUARD with food and resume a monthly dosing schedule.

Treatment with ACUGUARD may begin at any time of the year, preferably starting one month before fleas become active and continuing monthly through the end of flea season. In areas where fleas are common year-round, monthly treatment with ACUGUARD should continue the entire year without interruption.

To minimize the likelihood of flea reinfestations, it is important to treat all animals within a household with an approved flea protection product.

Contraindications:

There are no known contraindications for the use of ACUGUARD.

Warnings:

Not for human use. Keep this and all drugs out of the reach of children.

Precautions:

Use with caution with concomitant extra-label use of ivermectin (see ADVERSE REACTIONS).

The safe use of ACUGUARD in breeding, pregnant, or lactating cats has not been evaluated.

Adverse Reactions:

In a well-controlled US field study, which included a total of 211 cats (139 treated with ACUGUARD and 72 treated with an active topical control once a month for 3 treatments), no serious adverse reactions were attributed to the administration of ACUGUARD.

Over the 90-day study period, all observations of potential adverse reactions were recorded. Reactions that occurred at an incidence > 1% within any of the 3 months of observations are presented in the following table. The most frequently reported adverse reaction in cats was vomiting.

Percentage of Cats (%) with Adverse Reactions

	Month 1		Month 2		Month 3	
	ACUGUARD (n=139)	Active Topical Control (n=72)	ACUGUARD (n=135)	Active Topical Control (n=69)	ACUGUARD (n=132)	Active Topical Control (n=67)
Vomiting	14.4	1.4	14.8	1.4	13.6	4.5
Lethargy	3.6	0.0	0.7	0.0	1.5	1.5
Anorexia	2.2	0.0	0.7	0.0	2.3	1.5
Weight Loss	1.4	0.0	0.0	0.0	3.0	0.0
Diarrhea	1.4	1.4	0.7	2.9	2.3	1.5

Over the 3-month (3-dose) study, vomiting occurred on the day of or the day after at least one dose in 28.1% (39/139) of the cats treated with ACUGUARD and in 2.8% (2/72) of the cats treated with the active topical control. Three of the 139 cats treated with ACUGUARD vomited on the day of or the day after all three doses.

Two cats that received extra-label topical ivermectin on Day -1 of the field study developed lethargy on Day 1 after ACUGUARD administration on Day 0.

For technical assistance or to report suspected adverse drug events, call 1-888-545-5973. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or <http://www.fda.gov/AnimalVeterinary/SafetyHealth>

Mode of Action:

The primary target of action of ACUGUARD in insects is an activation of nicotinic acetylcholine receptors (nAChRs). Spinosad does not interact with known binding sites of other nicotinic or GABAergic insecticides such as neonicotinoids, fiproles, milbemycins, avermectins, and cyclodienes. Insects treated with spinosad show involuntary muscle contractions and tremors resulting from activation of motor neurons. Prolonged spinosad-induced hyperexcitation results in prostration, paralysis, and flea death. The selective toxicity of spinosad

between insects and vertebrates may be conferred by the differential sensitivity of the insect versus vertebrate nAChRs.

Effectiveness:

In a well-controlled laboratory study, ACUGUARD began to kill fleas 30 minutes after administration and demonstrated 98% effectiveness within 4 hours. ACUGUARD kills fleas before they can lay eggs. In a separate well-controlled laboratory study, ACUGUARD demonstrated 100% effectiveness on the first day following treatment and >90% effectiveness on Day 30.

If a severe environmental infestation exists, fleas may persist for a period of time after dose administration due to the emergence of adult fleas from pupae already in the environment.

In a field study conducted in households with existing flea infestations, flea count reductions of 97.5% were observed one month after the first treatment and 99.3% after three monthly treatments with ACUGUARD. Cats with pre-existing signs of flea allergy dermatitis showed improvement in erythema, papules, scaling, alopecia, dermatitis/pyodermitis, and pruritus as a direct result of eliminating the fleas.

Animal Safety:

In a margin of safety study, ACUGUARD was administered orally to 14-week-old kittens at 1X, 3X, and 5X the upper half (75 – 100 mg/kg) of the therapeutic dose band for six monthly dosing intervals 28 days apart. Vomiting was observed across all groups, but was seen with greater frequency in cats in the treated groups; it did not increase with increasing doses. Loose stool was observed in all but the 3X treatment group. Food consumption was decreased in the 5X female cats. ACUGUARD was not associated with clinically significant changes in hematology, clinical chemistry, coagulation, or urinalysis parameters. Cats administered ACUGUARD once monthly for 6 months in the 3X and 5X dose groups demonstrated cytoplasmic vacuolation, consistent with phospholipidosis, in the liver, lung, and adrenal gland. The long term effects of phospholipidosis are unknown. The administration of ACUGUARD was not associated with any clinically significant, gross necropsy or histopathological changes.

In a well-controlled field study, ACUGUARD was administered safely in conjunction with other frequently used veterinary products, including tapeworm anthelmintics, antibiotics, and an approved heartworm preventative containing ivermectin. Hematology and clinical chemistry values were compared pre- and post-study and were unremarkable.

Storage Information:

Store at 20 to 25°C (68 to 77°F), excursions permitted between 15 to 30°C (59 to 86°F).

How Supplied:

ACUGUARD is available in four tablet sizes for use in cats: 90, 140, 270 or 560 mg. Each tablet size is available in color-coded packages of 6 tablets.