VETRISHIELD PLUS- ivermectin/pyrantel tablet, chewable VetOne

VetriShield Plus (ivermectin/pyrantel pamoate) Flavored Chewables

See your veterinarian for more VetriShield Plus[™] Flavored Chewables

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

INDICATIONS:

For use in dogs to prevent canine heartworm disease by eliminating the tissue stage of heartworm larvae (*Dirofilaria immitis*) for a month (30 days) after infection and for the treatment and control of roundworms (*Toxocara canis, Toxascaris leonina*) and hookworms (*Ancylostoma caninum, Uncinaria stenocephala, Ancylostoma braziliense*).

DOSAGE:

VetriShield Plus[™] (ivermectin/pyrantel) Flavored Chewables should be administered orally at monthly intervals at the recommended minimum dose level of 6 mcg of ivermectin per kilogram (2.72 mcg/lb) and 5 mg of pyrantel (as pamoate salt) per kg (2.27 mg/lb) of body weight. The recommended dosing schedule for prevention of canine heartworm disease and for the treatment and control of roundworms and hookworms is as follows:

Dog Weight	Flavored Chewable Per Month	Ivermectin Content	Pyrantel Content
Up to 25 lbs	1	68 mcg	57 mg
26 to 50 lbs	1	136 mcg	114 mg
51 to 100 lbs	1	272 mcg	227 mg

VetriShield Plus[™] Flavored Chewables are recommended for dogs 6 weeks of age and older. For dogs over 100 lbs use the appropriate combination of these Flavored Chewables.

ADMINISTRATION:

Remove only one chewable at a time from the foil-backed blister card. Return the card with the remaining chewables to its box to protect the product from light. Because most dogs find VetriShield Plus[™] Flavored Chewables palatable, the product can be offered to the dog by hand. Alternatively, it may be added intact to a small amount of dog food. The chewable should be administered in a manner that encourages the dog to chew, rather than to swallow without chewing. Chewables may be broken into pieces and fed to dogs that normally swallow treats whole.

Care should be taken that the dog consumes the complete dose, and treated animals should be observed for a few minutes after administration to ensure that part of the dose is not lost or rejected. If it is suspected that any of the dose has been lost, redosing is recommended. VetriShield Plus [™] Flavored Chewables should be given at monthly intervals during the period of the year when mosquitoes (vectors), potentially carrying infective heartworm larvae, are active. The initial dose must be given within a month (30 days) after the dog's first exposure to mosquitoes.

The final dose must be given within a month (30 days) after the dog's last exposure to mosquitoes. When replacing another heartworm preventive product in a heartworm disease preventive program, the first dose of VetriShield Plus[™] Flavored Chewables must be given within a month (30 days) of the last dose of the former medication.

If the interval between doses exceeds a month (30 days), the efficacy of ivermectin can be reduced. Therefore, for optimal performance, the flavored chewable must be given once a month on or about the same day of the month. If treatment is delayed, whether by a few days or many, immediate treatment with VetriShield Plus[™] Flavored Chewables and resumption of the recommended dosing regimen minimizes the opportunity for the development of adult heartworms.

Monthly treatment with VetriShield Plus[™] Flavored Chewables also provides effective treatment and control of roundworms (*T. canis, T. leonina*) and hookworms (*A. caninum, U. stenocephala, A. braziliense*). Clients should be advised of measures to be taken to prevent reinfection with intestinal parasites.

EFFICACY:

VetriShield Plus TM Flavored Chewables, given orally using the recommended dose and regimen, are effective against the tissue larval stage of *D. immitis* for a month (30 days) after infection and, as a result, prevent the development of the adult stage. VetriShield Plus TM Flavored Chewables are also effective against canine roundworms (*T. canis, T. leonina*) and hookworms (*A. caninum, U. stenocephala, A. braziliense*).

ACCEPTABILITY: In a trial in client-owned dogs, VetriShield Plus[™] Flavored Chewables were shown to be a palatable oral dosage form consumed at first offering by the majority of dogs.

PRECAUTIONS:

All dogs should be tested for existing heartworm infection before starting treatment with VetriShield Plus [™] Flavored Chewables, which are not effective against adult *D. immitis*. Infected dogs must be treated to remove adult heartworms and microfilariae before initiating a program with VetriShield Plus [™] Flavored Chewables.

While some microfilariae may be killed by the ivermectin in VetriShield Plus[™] Flavored Chewables at the recommended dose level, VetriShield Plus[™] Flavored Chewables are not effective for microfilariae clearance. A mild hypersensitivity-type reaction, presumably due to dead or dying microfilariae and particularly involving a transient diarrhea, has been observed in clinical trials with ivermectin alone after treatment of some dogs that have circulating microfilariae.

Keep this and all drugs out of the reach of children.

In case of ingestion by humans, clients should be advised to contact a physician immediately. Physicians may contact a Poison Control Center for advice concerning cases of ingestion by humans.

STORAGE:

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

Protect product from light.

WARNINGS:

Use product on or before its expiration date.

Discard or return unused tablets.

ADVERSE REACTIONS:

In clinical trials with ivermectin/pyrantel, vomiting or diarrhea within 24 hours of dosing was rarely observed (1.1% of administered doses). The following adverse reactions have been reported following the use of ivermectin: Depression/lethargy, vomiting, anorexia, diarrhea, mydriasis, ataxia, staggering, convulsions and hypersalivation.

To report suspected adverse drug events, for technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact Virbac AH, Inc at 1-800-338-3659 or us.virbac.com. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/reportanimalae.

SAFETY:

Studies with ivermectin indicate that certain dogs of the Collie breed are more sensitive to the effects of ivermectin administered at elevated dose levels (more than 16 times the target use level of 6 mcg/kg) than dogs of other breeds. At elevated doses, sensitive dogs showed adverse reactions which included mydriasis, depression, ataxia, tremors, drooling, paresis, recumbency, excitability, stupor, coma and death. Ivermectin demonstrated no signs of toxicity at 10 times the recommended dose (60 mcg/kg) in sensitive Collies. Results of these trials and bioequivalency studies, support the safety of ivermectin products in dogs, including Collies, when used as recommended.

Ivermectin/pyrantel has shown a wide margin of safety at the recommended dose level in dogs, including pregnant or breeding bitches, stud dogs and puppies aged 6 or more weeks. In clinical trials, many commonly used flea collars, dips, shampoos, anthelmintics, antibiotics, vaccines and steroid preparations have been administered with ivermectin/pyrantel in a heartworm disease preventive program.

In one trial, where some pups had parvovirus, there was a marginal reduction in efficacy against intestinal nematodes, possibly due to a change in intestinal transit time.

HOW SUPPLIED:

VetriShield Plus[™] Flavored Chewables are available in three dosage strengths (See **DOSAGE** section) for dogs of different weights. Each strength comes in a box of 6

tablets, packed 10 boxes per display box. Approved by FDA under ANADA # 200-302 Manufactured by: Virbac AH, Inc. Fort Worth, TX 76161, USA Distributed by: MWI Boise, ID 83705 www.VetOne.net

Rev. 10/23



Flavored Che

26 - 50 lbs

(ivermectin/pyrantel)

51-100

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V1 620114

V1 620113

Product Type

Approved by FDA under ANADA # 200-302

ivermectin/pyrantel tablet, chewable

VETRISHIELD PLUS

Product Information

PRESCRIPTION ANIMAL DRUG

Item Code (Source)

NDC:13985-951

Active Ingredient/Active Moiety									
Ingredient Name						Basis of Strength			Strength
IVERMECTIN (UNII: 8883YP2R6D) (IVERMECTIN - UNII:8883YP2R6D)						IVERMEC	CTIN		0.068 mg
PYRANTEL PAMOATE (UNII: 81BK194Z5M) (PYRANTEL - UNII:4QIH0N49E7)					E7)	7) PYRANTEL .057 r			.057 mg
Inactive Ingredi	ents								
		Ingredient Nam	е					Strengt	h
WATER (UNII: 059QF0	(O0R)	5							
Product Charact									
	erist		-						
Color		brown	Sco			no score			
Shape		ROUND	Size			16mm			
Flavor			Imp	rint Code					
Contains									
Packaging									
# Item Code	Pa	ckage Descripti	on	Marketing	J Start [Date	Ma	rketing I	Ind Date
1 NDC:13985-951-25	1 in 1	l BOX							
1	6 in 2	L BLISTER PACK							
Marketing Information									
Marketing Category	Арр	lication Number Citation		onograph		eting S [.] Date	tart		eting End Date
ANADA	ANADA	200302			03/01/20	19			

VETRISHIELD PLUS								
ivermectin/pyrantel tablet, chewable								
Product Information								
Product Type	PRESCRIPTION ANIMAL DRUG	RESCRIPTION ANIMAL DRUG Item Code (Source) NDC:13985-						
Route of Administration	oral							
Active Ingredient/Active Moiety								
Ingre	Basis of Strength		Strength					
IVERMECTIN (UNII: 8883YP2R6D) (IVERMECTIN		.136 mg				
PYRANTEL PAMOATE (UNII: 81BK194Z5M) (PYRANTEL - UNII:4QIH0N49E7) PYRANTEL .114 mg								

Inactive Ingredie								
	Ing	redient Name				Strengt	h	
WATER (UNII: 059QF0K	(O0R)							
Product Charact	eristics							
Color	brow	wn S	Score		n	o score		
Shape	ROU					16mm		
Flavor		li	mprint Code					
Contains								
Packaging								
# Item Code	Packa	ge Descriptio	n Marketin	g Start Da	te Mar	ketina I	End Date	
1 NDC:13985-969-50	1 in 1 BO			g otart Da				
1	6 in 1 BLIS	STER PACK						
Marketing In	format	ion						
Marketing In Marketing Category		ion tion Number or Citation	r Monograph		ng Start Ite		eting End Date	
Marketing Category		tion Number or Citation	r Monograph		-			
Marketing Category ANADA	Applicat ANADA2003 PLUS	tion Number of Citation 02	r Monograph	Da	-			
Marketing Category ANADA /ETRISHIELD /ermectin/pyrantel	Applicat ANADA2003 PLUS tablet, che	tion Number of Citation 02	r Monograph	Da	-			
Marketing Category ANADA /ETRISHIELD /ermectin/pyrantel Product Informa	Applicat ANADA20030 PLUS tablet, che	tion Number or Citation 02 ewable		Da 03/01/2019	ite		Date	
Marketing Category ANADA /ETRISHIELD /ermectin/pyrantel Product Informa Product Type	Applicat ANADA20030 PLUS tablet, che	tion Number or Citation 02 ewable PRESCRIPTION AI		Da	ite			
Marketing Category ANADA /ETRISHIELD /ermectin/pyrantel Product Informa Product Type	Applicat ANADA20030 PLUS tablet, che	tion Number or Citation 02 ewable		Da 03/01/2019	ite		Date	
Marketing Category ANADA /ETRISHIELD /ermectin/pyrantel Product Informa Product Type Route of Administr	Applicat ANADA2003 PLUS tablet, che ation	tion Number or Citation 02 ewable PRESCRIPTION AI oral		Da 03/01/2019	ite		Date	
Marketing Category ANADA /ETRISHIELD /ermectin/pyrantel Product Informa Product Type Route of Administr	Application ANADA2003 PLUS tablet, che ation ration	tion Number or Citation 02 ewable PRESCRIPTION AI oral		Da 03/01/2019	ite	NDC: :	Date	
Category	Application ANADA2003 PLUS tablet, che ation ration t/Active Ingre	tion Number or Citation 02 ewable PRESCRIPTION AI oral Moiety edient Name	NIMAL DRUG	Da 03/01/2019	(Source)	NDC: :	Date 13985-970	

Inactive Ingredients								
	Ingredient Name							
WATER (UNII: 059QF0KO0R)								
Product Characteristics								
Color	brown	Score		no score				

Shape	ROUND	Size		16	mm		
Flavor		Imprint Code					
Contains							
Packaging							
# Item Code	Package Description	on Marketing	J Start Date	Mark	eting End Date		
1 NDC:13985-970-10	1 in 1 BOX						
1	6 in 1 BLISTER PACK						
Marketing Information							
Marketing Category	Application Number o Citation		Marketing St Date	art	Marketing End Date		
ANADA	ANADA200302		03/01/2019				

Labeler - VetOne (019926120)

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