PETARMOR CAPACTION- nitenpyram tablet Sergeant's Pet Care Products LLC

PETARMOR® CAPACTION® (nitenpyram)

Capaction is an oral tablet for dogs, puppies, cats and kittens 2 pounds of body weight or greater and 4 weeks of age and older.

ACTIVE INGREDIENTS

CAPACTION Tablets contain 11.4 or 57.0 mg of nitenpyram, which belongs to the chemical class of neonicotinoids. Nitenpyram kills adult fleas.

WARNINGS

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

DIRECTIONS

CAPACTION Tablets kill adult fleas and are indicated for the treatment of flea infestations on dogs, puppies, cats and kittens 2 pounds of body weight or greater and 4 weeks of age and older.

A single dose of CAPACTION should kill the adult fleas on your pet. If your pet gets reinfested with fleas, you can safely give another dose as often as once per day.

To give CAPACTION Tablets, place the pill directly in your pet's mouth or hide it in food. If you hide the pill in food, watch closely to make sure your pet swallows the pill. If you are not sure that your pet swallowed the pill, it is safe to give a second pill.

Treat all infested pets in the household. Fleas can reproduce on untreated pets and allow infestations to persist.

DOSAGE

CAPACTION Tablets should be administered according to the following schedule. **Weigh** your pet prior to administration to ensure proper dosage. Do not administer to pets under 2 pounds.

Recommended Dosage Schedule

Species	Body Weight	Dose	Nitenpyram Per Tablet
Dog or Cat	2-25 lbs.	One Tablet	11.4 mg
Dog	25.1-125 lbs.	One Tablet	57.0 mg

ADVERSE REACTIONS

Pre-approval laboratory and clinical studies showed that CAPACTION Tablets are safe for use in dogs and cats, puppies and kittens **2 pounds of body weight or greater and**

4 weeks of age and older. (See Post-Approval Experience section).

Post-Approval Experience (Rev. 2011):

The following adverse events are based on post-approval adverse drug experience reporting. Not all adverse reactions are reported to FDA CVM. It is not always possible to reliably estimate the adverse event frequency or establish a causal relationship to product exposure using this data. The following adverse events are listed in decreasing order of reporting frequency.

CATS: hyperactivity, panting, lethargy, itching, vocalization, vomiting, fever, decreased appetite, nervousness, diarrhea, difficulty breathing, salivation, incoordination, seizures, pupil dilation, increased heart rate, and trembling.

DOGS: lethargy/depression, vomiting, itching, decreased appetite, diarrhea, hyperactivity, incoordination, trembling, seizures, panting, allergic reactions including hives, vocalization, salivation, fever, and nervousness.

The frequency of serious signs, including neurologic signs and death, was greater in animals under 2 pounds of body weight, less than 8 weeks of age, and/or reported to be in poor body condition. In some instances, birth defects and fetal/neonatal loss were reported after treatment of pregnant and/or lactating animals.

To report adverse effects, access medical information, or obtain additional product information call 1-800-781-4738. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/reportanimalae.

For a complete listing of adverse reactions for nitenpyram reported to the CVM see:

 $\underline{http://www.fda.gov/AnimalVeterinary/SafetyHealth/ProductSafetyInformation}$

OTHER INFORMATION

CAPACTION Tablets begin working within 30 minutes. In studies, CAPACTION achieved greater than 90% effectiveness against adult fleas on dogs within 4 hours and cats within 6 hours.

CAPACTION Tablets are safe for pregnant or nursing dogs and cats (See Post-Approval Experience section).

When using this product, you may notice that your dog or cat will start scratching itself as fleas begin to die. The scratching behavior is temporary and is a reaction to the fleas, not the drug. In cats and dogs, this may present as transient signs of hyperactivity, panting, vocalization and excessive grooming/licking.

CAPACTION Tablets kill adult fleas that cause flea allergy dermatitis (FAD).

CAPACTION Tablets may be used together with other products, including heartworm preventives, corticosteroids, antibiotics, vaccines, de-worming medications, shampoos and other flea products.

FLEA INFESTATIONS ON DOGS AND CATS

In addition to the common nuisance irritations associated with infestations, fleas can be responsible for skin conditions in your pet such as flea allergy dermatitis (FAD) in the dog and miliary dermatitis in the cat. Also, fleas transmit other parasites, including tapeworms. The control of flea infestations is important to your pet's health and also reduces the problems associated with these parasites.

CAPACTION Tablets do not have an effect on fleas in the pet's environment. You may need to treat more than one time because immature fleas in and around the home will continue to develop into adults that can reinfest your pet.

The following diagram illustrates the flea's life cycle and where CAPACTION Tablets work:

LIFE CYCLE OF FLEA

leas can be a problem because they reproduce so rapidly. A single female flea may produce up to 2,000 eggs over her lifetime. Eggs hatch and can develop into adults within only three weeks. Adult female fleas feed by ingesting blood from your pet and subsequently lay eggs, which drop off your pet's coat. Within days, larvae hatch from the eggs and live undetected in your pet's surroundings, such as the carpet, bedding and other protected areas. Flea larvae spin a cocoon, and, when appropriately stimulated, a young adult flea emerges and jumps onto your pet to continue the life cycle. When these new fleas are seen on your pet, treat with CAPACTION Tablets.

After reading this insert, if you have any questions about flea control or medical problems associated with flea infestations, consult your veterinarian, who is your pet's health care expert.

STORAGE CONDITIONS

Store at controlled room temperature, between 59° and 77°F (15°-25°C).

For questions, comments, technical assistance or to report a suspected adverse event please call 1-800-781-4738

Approved by FDA under NADA # 141-175

PETIQ

G002429 PetArmor Capaction Carton Dog 2-25 lbs. 6 ct





6TABLETS (11.4 mg each)



18A

SH10311

Begins working within 30 minutes

For Oral Use







For DOGS 2-25 lbs



Secretions or Comments 98 8874-187-008-1 :||D) expel

lotin paye questions about alle a most se que y ll en a lot with the a no consequence of the contest of the con CAPACTION kills adult fleas that couse flea alleigy deimotitis (FAD).

Begins working within 30 minutes. In studies, CAPACION achieved greater than 90% et les tiveness against adult fleas god nog within 4 hours.





contract with the state of the

DIRECTIONS:
As might be confident with the distribution of during the distribution of during the distribution of during the consistency of distribution of during the during the

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

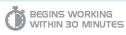


Monufoctured for: Sergeont's Pet Core Products, LLC dbo PetlQ Omoha, NE 68138 Product of Switzerland

(menuquein)



CAPACTION (nitenpyram)



For DOGS 2-25 lbs





5 8

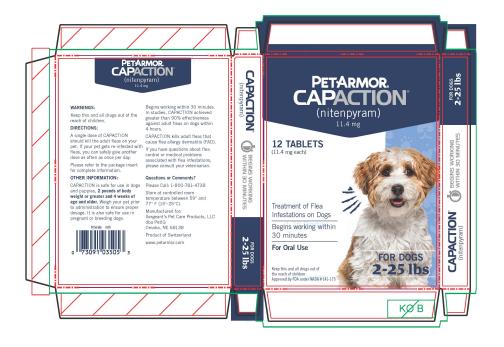
G002486 PetArmor Capaction Carton Dog 2-25 lbs. 6 ct





P056486 PetArmor Capaction Carton Dog 2-26 lbs. 12 ct





G002431 PetArmor Capaction Carton Cat 2-25 lbs. 6 ct





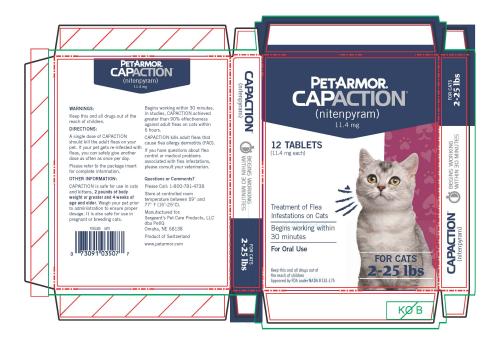
G002488 PetArmor Capaction Carton Cat 2-25 lbs. 6 ct



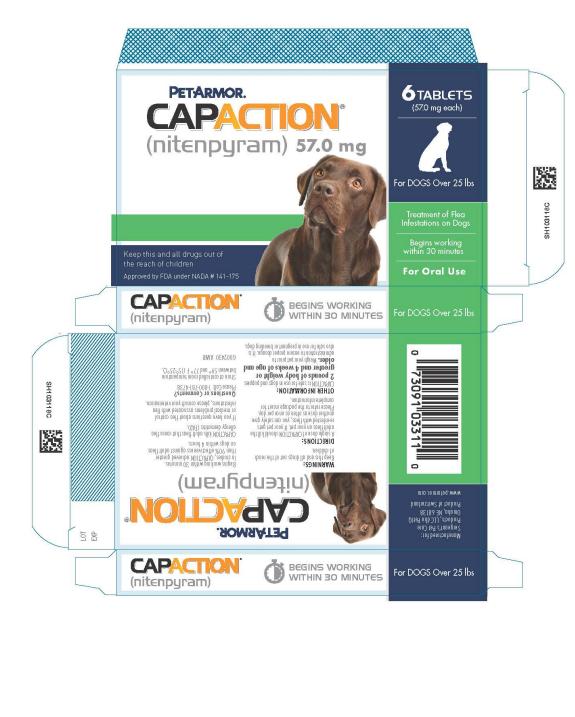


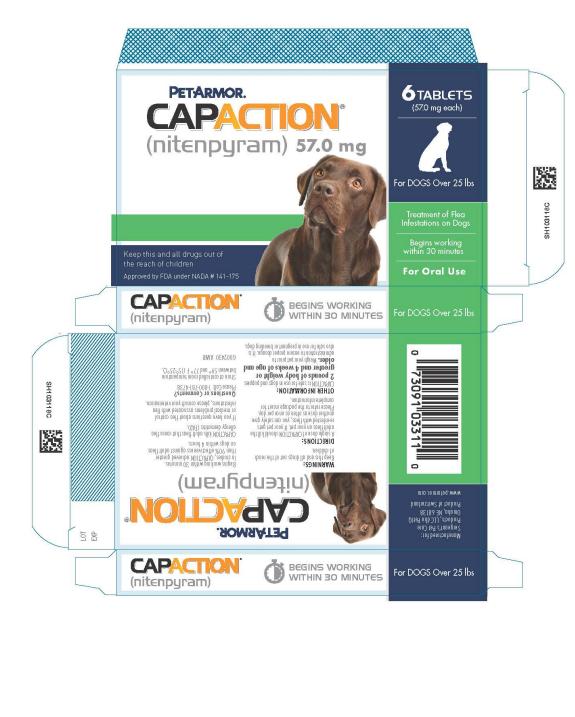
P056488 PetArmor Capaction Carton Cat 2-25 lbs. 12 ct





G002430 PetArmor Capaction Carton Dog Over 25 lbs. 6 ct



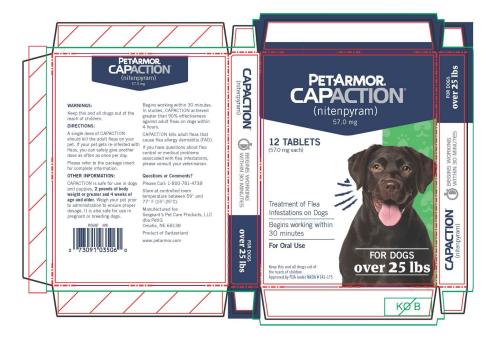


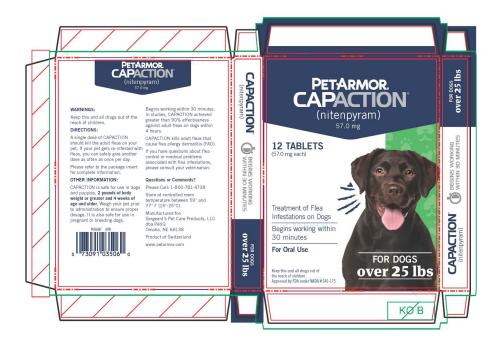
G002487 PetArmor Capaction Carton Dog Over 25 lbs. 6 ct





P056487 PetArmor Capaction Carton Dog Over 25 lbs. 12 ct





PETARMOR CAPACTION

nitenpyram tablet

Droduct	Information	

Product Type OTC ANIMAL DRUG Item Code (Source) NDC:21091-141

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NITENPYRAM (LINII: 3A837VZ81Y) (NITENPYRAM - LINII: 3A837VZ81Y)	NITENPYRAM	11 4 ma

Inactive Ingredients	
Ingredient Name	Strength
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics				
Color	white (to yellow)	Score	no score	
Shape	ROUND (biconvex beveled edges)	Size	6mm	
Flavor		Imprint Code	RB;CG	
Contains				

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21091-141-01	1 in 1 CARTON		
1		6 in 1 BLISTER PACK		
2	NDC:21091-141-02	2 in 1 CARTON		
2		6 in 1 BLISTER PACK		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA141175	10/12/2021	

PETARMOR CAPACTION

nitenpyram tablet

Product Information			
Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:21091-142
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
NITENPYRAM (UNII: 3A837VZ81Y) (NITENPYRAM - UNII:3A837VZ81Y)	NITENPYRAM	57.0 mg

Inactive Ingredients	
Ingredient Name	Strength
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics

Color	white (to yellow)	Score	no score
Shape	ROUND (biconvex beveled edges)	Size	11mm
Flavor		Imprint Code	HIH;CG
Contains			

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:21091-142-01	1 in 1 CARTON				
1		6 in 1 BLISTER PACK				
2	NDC:21091-142-02	2 in 1 CARTON				
2		6 in 1 BLISTER PACK				

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
NADA	NADA141175	10/12/2021		

Labeler - Sergeant's Pet Care Products LLC (876995171)

Establishment				
Name	Address	ID/FEI	Business Operations	
Elanco Clinton Laboratories		039138631	manufacture, analysis, label, pack	

Establishment				
Name	Address	ID/FEI	Business Operations	
Elanco France SAS		736833104	manufacture, analysis, label, pack	

Establishment			
Name	Address	ID/FEI	Business Operations
DOTTIKON EXCLUSIVE SYNTHESIS AG		480000413	api manufacture

Establishment				
Name	Address	ID/FEI	Business Operations	
Tetragenx Animal Health ULC		203877183	manufacture, analysis, label, pack	

Revised: 4/2023 Sergeant's Pet Care Products LLC