

CAPSTAR- nitenpyram tablet
Sergeant's Pet Care Products LLC

CAPSTAR®
(nitenpyram)

CAPSTAR 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 Ingredient

CAPSTAR 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

CAPSTAR 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 CAPSTAR should kill the adult fleas on your pet. If your pet gets re-infested with fleas, you can safely give another dose as often as once per day.

To give CAPSTAR 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

CAPSTAR 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 CAPSTAR 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:

<http://www.fda.gov/AnimalVeterinary/SafetyHealth/ProductSafetyInformation>

For technical assistance call 1-800-781-4738.

Other Information

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

CAPSTAR 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.

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

CAPSTAR 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.

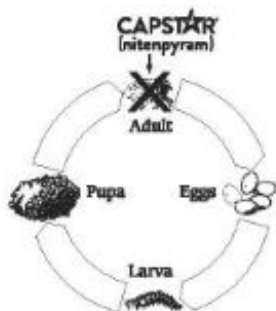
CAPSTAR Tablets do not have an effect on fleas in the pet's environment. You may need to treat more than one time because immature fleas in and around the home will continue to develop into adults that can reinfest your pet.

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

Life Cycle of the Flea

Fleas 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 CAPSTAR 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).

Questions? Comments? Please Call 1-800-781-4738

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

Visit our web site at www.capstarpet.com

Approved by FDA under NADA # 141-175

PETIQ

G002477 Capstar for Dogs 2-25 lbs. 6ct Carton



G002479 Capstar for Cats 2-25 lbs. 6ct Carton



G002478 Capstar for Dogs Over 25 lbs. 6ct Carton



G003117 Capstar for Cats & Dogs 2-25 lbs. Clinic Pak 60ct



G003118 Capstar for Dogs Over 25 lbs. Clinic Pak 60ct



CAPSTAR
nitenpyram tablet

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:21091-175
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NITENPYRAM (UNII: 3A837VZ81Y) (NITENPYRAM - UNII:3A837VZ81Y)	NITENPYRAM	11.4 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	6mm
Flavor		Imprint Code	RB;CG
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21091-175-01	1 in 1 CARTON		
1		6 in 1 BLISTER PACK		
2	NDC:21091-175-03	10 in 1 BOX		
2		6 in 1 BLISTER PACK		
3	NDC:21091-175-04	10 in 1 BOX		
3	NDC:21091-175-01	1 in 1 CARTON		
3		6 in 1 BLISTER PACK		
4	NDC:21091-175-05	2 in 1 CELLO PACK		
4	NDC:21091-175-01	1 in 1 CARTON		
4		6 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA141175	10/11/2021	

CAPSTAR

nitenpyram tablet

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:21091-178
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	HH;CG
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21091-178-01	1 in 1 CARTON		
1		6 in 1 BLISTER PACK		
2	NDC:21091-178-03	10 in 1 BOX		
2		6 in 1 BLISTER PACK		
3	NDC:21091-178-04	10 in 1 BOX		
3	NDC:21091-178-01	1 in 1 CARTON		
3		6 in 1 BLISTER PACK		
4	NDC:21091-178-05	2 in 1 CELLO PACK		
4	NDC:21091-178-01	1 in 1 CARTON		
4		6 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA141175	10/01/2021	

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

Establishment

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

Establishment

Name	Address	ID/FEI	Business Operations
Vetio Animal Health ULC		243313714	manufacture, analysis, label, pack

Revised: 12/2024

Sergeant's Pet Care Products LLC