

**CAPSTAR- nitenpyram tablet**  
**Sergeant's Pet Care Products LLC**

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**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**

| <b>Species</b> | <b>Body Weight</b> | <b>Dose</b> | <b>Nitenpyram Per Tablet</b> |
|----------------|--------------------|-------------|------------------------------|
| 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.

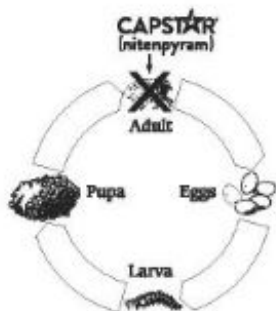
CAPSTAR Tablets do not have an effect on fleas in the pet's environment. You may need to treat more than one time because immature fleas in and around the home will continue to develop into adults that can reinfest your pet.

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](http://www.capstarpet.com)

Approved by FDA under NADA # 141-175

**PETIQ**

**G002376 Capstar for Dogs 2-25 lbs. 6ct Carton**



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

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**P056482 Capstar for Dogs 2-25 lbs. 12ct Carton**



Begins working within 30 minutes

For dogs **2-25 lbs**

**CAPSTAR®**  
(nitenpyram)

**CAPSTAR®**  
(nitenpyram)  
11.4 mg



Treatment of flea infestations on dogs



For oral use



Begins working within 30 minutes



For dogs **2-25 lbs** | **12 tablets (11.4 mg each)**

Keep this and all drugs out of the reach of children  
Approved by FDA under NADA # 141-175

LOT

0.813



Begins working within 30 minutes

For dogs **2-25 lbs**

**CAPSTAR®**  
(nitenpyram)

0.625

0.625

**CAPSTAR®**  
(nitenpyram)

0 73091 03135 2

**PETIQ**

P056482 A01R

Product of Switzerland. www.capstarpet.com  
Manufactured for: Sargant's Pet Care Products, LLC dba PetIQ, Omaha, Nebraska 68138, USA  
Please call 1-800-781-4738. Store at controlled room temperature, between 59° and 77°F (15°-25°C).

**QUESTIONS OR COMMENTS?**

- CAPSTAR is safe for use in dogs and puppies 2 pounds of body weight or greater and 4 weeks of age and older. Weigh your pet prior to administration to ensure proper dosage. It is also safe for use in pregnant or breeding dogs.
- CAPSTAR kills adult fleas that cause flea allergy dermatitis (FAD).
- CAPSTAR kills adult fleas on dogs within 4 hours.
- CAPSTAR achieved greater than 90% effectiveness against adult fleas on dogs within 30 minutes. In studies, CAPSTAR achieved greater than 90% effectiveness against adult fleas on dogs within 4 hours.
- CAPSTAR kills adult fleas that cause flea allergy dermatitis (FAD).
- If you have questions about flea control or medical problems associated with flea infestations, please consult your veterinarian.

**OTHER INFORMATION:**

A single dose of CAPSTAR is safe for use in dogs and puppies 2 pounds of body weight or greater and 4 weeks of age and older. Weigh your pet prior to administration to ensure proper dosage. It is also safe for use in pregnant or breeding dogs.

**DIRECTIONS:**

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

**G002378 Capstar for Cats 2-25 lbs. 6ct Carton**

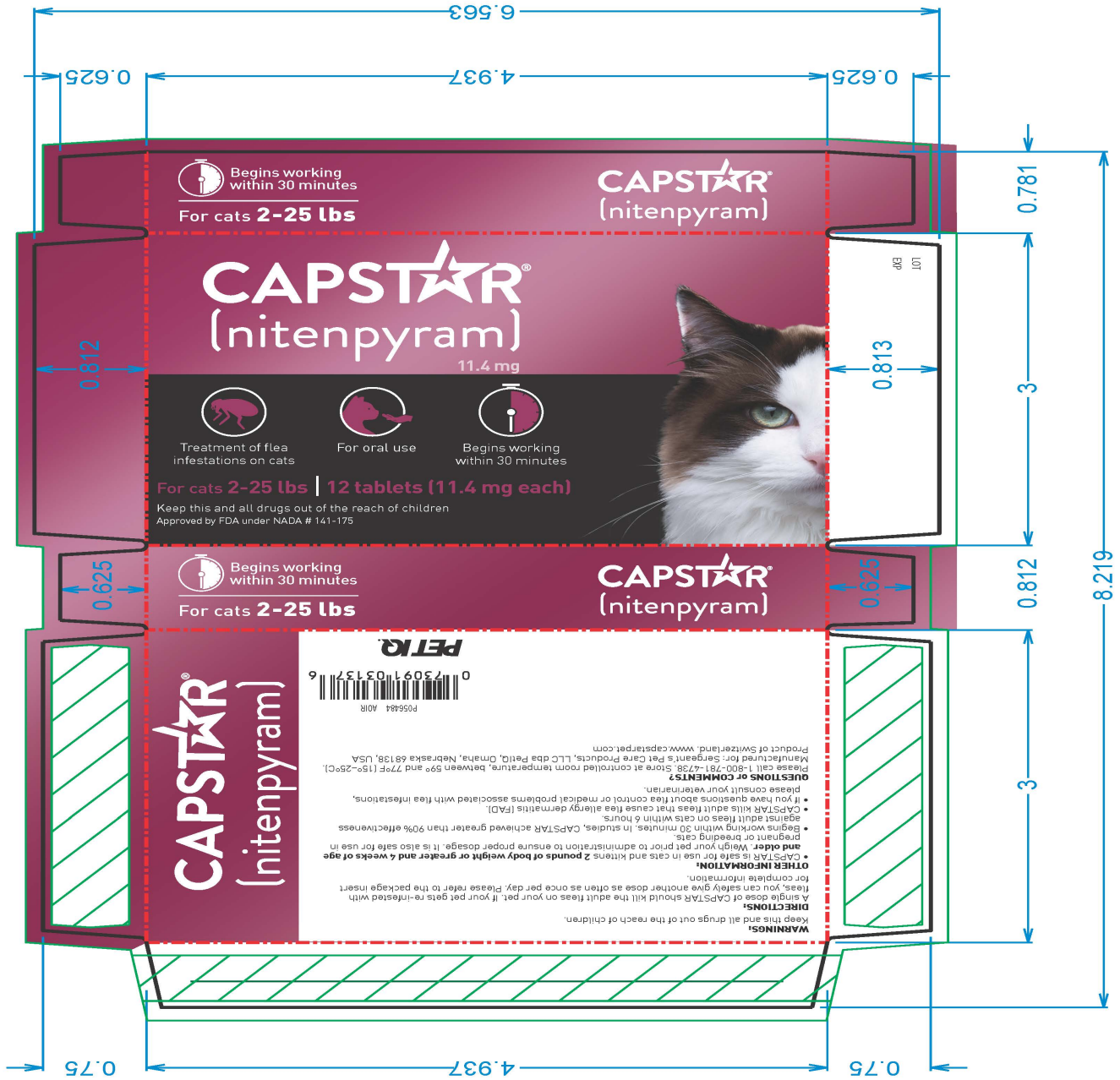


**G002479 Capstar for Cats 2-25 lbs. 6ct Carton**



**P056484 Capstar for Cats 2-25 lbs. 12ct Carton**





**G002377 Capstar for Dogs Over 25 lbs. 6ct Carton**



**G002478 Capstar for Dogs Over 25 lbs. 6ct Carton**



**P056483 Capstar for Dogs Over 25 lbs. 12 ct Carton**





Begins working within 30 minutes

For dogs **over 25 lbs**

**CAPSTAR**  
(nitenpyram)

**CAPSTAR**  
(nitenpyram)  
57.0 mg



Treatment of flea infestations on dogs



For oral use



Begins working within 30 minutes

For dogs **over 25 lbs** | 12 tablets (57.0 mg each)

Keep this and all drugs out of the reach of children  
Approved by FDA under NADA # 141-175

LOT

0.813

0.612



Begins working within 30 minutes

For dogs **over 25 lbs**

**CAPSTAR**  
(nitenpyram)

0.625

0.625

**CAPSTAR**  
(nitenpyram)

**PETIQ**



P056483 A01R

Product of Switzerland and [www.capstarpet.com](http://www.capstarpet.com)  
Manufactured for: Sergeant's Pet Care Products, LLC dba PetIQ, Omaha, Nebraska 68138, USA  
Please call 1-800-781-4738. Store at controlled room temperature, between 59° and 77°F (15°-25°C).

**QUESTIONS OR COMMENTS?**

- If you have questions about flea control or medical problems associated with flea infestations, please consult your veterinarian.
- CAPSTAR kills adult fleas that cause flea allergy dermatitis (FAD).
- CAPSTAR kills adult fleas on dogs within 4 hours.
- Begins working within 30 minutes. In studies, CAPSTAR achieved greater than 90% effectiveness against adult fleas on dogs within 4 hours.
- CAPSTAR is safe for use in dogs and puppies 2 pounds of body weight or greater and 4 weeks of age and older. Weigh your pet prior to administration to ensure proper dosage. It is also safe for use in pregnant or breeding dogs.

**OTHER INFORMATION:**

As single doses 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. Please refer to the package insert for complete information.

**DIRECTIONS:**

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

**WARNINGS:**



# G002381 Capstar for Cats & Dogs 2-25 lbs. Clinic Pak 60ct



# G002481 Capstar for Cats & Dogs 2-25 lbs. Clinic Pak 60ct



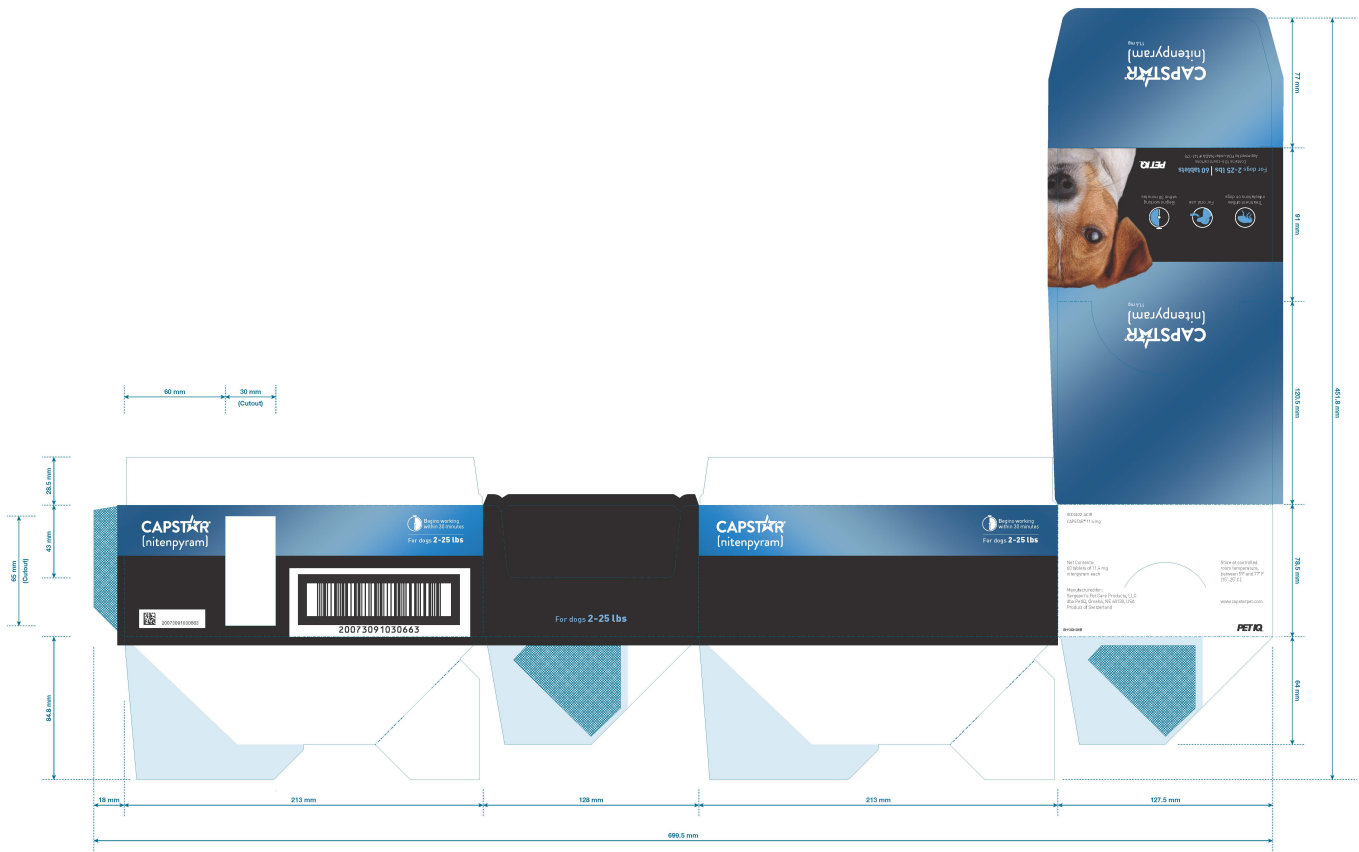
**G002382 Capstar for Dogs Over 25 lbs. Clinic Pak 60ct**

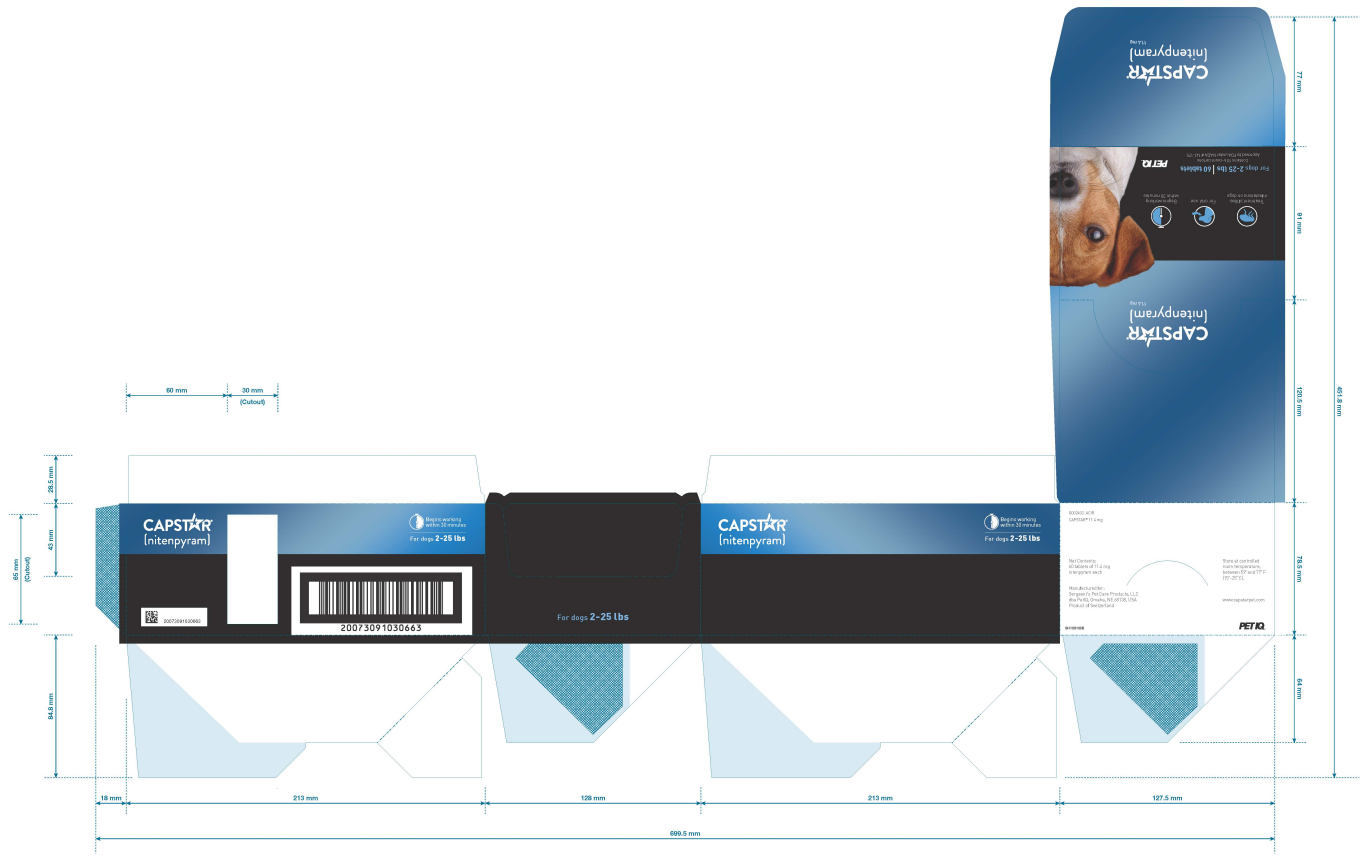


**G002482 Capstar for Dogs Over 25 lbs. Clinic Pak 60ct**



**G002402 Capstar for Dogs 2-25 lbs. Display Carton 60ct**





## G002393 Capstar for Cats 2-25 lbs. Display Carton 60ct





**G002403 Capstar for Dogs Over 25 lbs. Display Carton 60ct**





## CAPSTAR

nitenpyram tablet

### Product Information

|                                |                 |                           |               |
|--------------------------------|-----------------|---------------------------|---------------|
| <b>Product Type</b>            | OTC ANIMAL DRUG | <b>Item Code (Source)</b> | NDC:21091-175 |
| <b>Route of Administration</b> | ORAL            |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength | Strength |
|---|-------------------|----------|
| <b>NITENPYRAM</b> (UNII: 3A837VZ81Y) (NITENPYRAM - UNII:3A837VZ81Y) | NITENPYRAM        | 11.4 mg  |

### Inactive Ingredients

| Ingredient Name                                       | Strength |
|---|----------|
| <b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)         |          |
| <b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U) |          |
| <b>STARCH, CORN</b> (UNII: O8232NY3S)                 |          |
| <b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)             |          |
| <b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)          |          |

### Product Characteristics

|                 |                                |                     |          |
|-----------------|--------------------------------|---------------------|----------|
| <b>Color</b>    | white (to yellow)              | <b>Score</b>        | no score |
| <b>Shape</b>    | ROUND (biconvex beveled edges) | <b>Size</b>         | 6mm      |
| <b>Flavor</b>   |                                | <b>Imprint Code</b> | RB;CG    |
| <b>Contains</b> |                                |                     |          |

### 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:21091-175-02 | 2 in 1 CARTON       |                      |                    |
| 2 |                  | 6 in 1 BLISTER PACK |                      |                    |
| 3 | NDC:21091-175-03 | 10 in 1 BOX         |                      |                    |
| 3 |                  | 6 in 1 BLISTER PACK |                      |                    |
| 4 | NDC:21091-175-04 | 10 in 1 BOX         |                      |                    |
| 4 | NDC:21091-175-01 | 1 in 1 CARTON       |                      |                    |
| 4 |                  | 6 in 1 BLISTER PACK |                      |                    |
| 5 | NDC:21091-175-05 | 2 in 1 CELLO PACK   |                      |                    |
| 5 | NDC:21091-175-01 | 1 in 1 CARTON       |                      |                    |
| 5 |                  | 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

|                                |                 |                           |               |
|--------------------------------|-----------------|---------------------------|---------------|
| <b>Product Type</b>            | OTC ANIMAL DRUG | <b>Item Code (Source)</b> | NDC:21091-178 |
| <b>Route of Administration</b> | ORAL            |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength | Strength |
|---|-------------------|----------|
| <b>NITENPYRAM</b> (UNII: 3A837VZ81Y) (NITENPYRAM - UNII:3A837VZ81Y) | NITENPYRAM        | 57.0 mg  |

### Inactive Ingredients

| Ingredient Name                                       | Strength |
|---|----------|
| <b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)         |          |
| <b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U) |          |
| <b>STARCH, CORN</b> (UNII: O8232NY3SJ)                |          |
| <b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)             |          |



MAGNESIUM STEARATE (UNII: 70097M6I30)

### Product Characteristics

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

### 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:21091-178-02 | 2 in 1 CARTON       |                      |                    |
| 2 |                  | 6 in 1 BLISTER PACK |                      |                    |
| 3 | NDC:21091-178-03 | 10 in 1 BOX         |                      |                    |
| 3 |                  | 6 in 1 BLISTER PACK |                      |                    |
| 4 | NDC:21091-178-04 | 10 in 1 BOX         |                      |                    |
| 4 | NDC:21091-178-01 | 1 in 1 CARTON       |                      |                    |
| 4 |                  | 6 in 1 BLISTER PACK |                      |                    |
| 5 | NDC:21091-178-05 | 2 in 1 CELLO PACK   |                      |                    |
| 5 | NDC:21091-178-01 | 1 in 1 CARTON       |                      |                    |
| 5 |                  | 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                |
|-----------------------------|---------|-----------|------------------------------------|
| 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, analysis |

### Establishment

| <b>Name</b>                 | <b>Address</b> | <b>ID/FEI</b> | <b>Business Operations</b>         |
|-----------------------------|----------------|---------------|------------------------------------|
| Tetragenx Animal Health ULC |                | 203877183     | manufacture, analysis, label, pack |

Revised: 4/2023

Sergeant's Pet Care Products LLC