Date of Authorization: September 3, 2026

# FREEDOM OF INFORMATION (FOI) SUMMARY

Original Emergency Use Authorization (EUA)

EUA 006688

CAPSTAR®

(nitenpyram)

Tablets

Dogs and Cats

Scope of Authorization: For the treatment and prevention of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in dogs, puppies, cats and kittens **2 pounds of body weight or greater and 4 weeks of age and older**.

Sponsored by:

Sergeant's Pet Care Products LLC

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# I. GENERAL INFORMATION

## A. File Number

EUA 006688

## B. Sponsor

Sergeant's Pet Care Products LLC
10077 S. 134th St.
Omaha, NE 68138

Drug Labeler Code: 021091

## C. Proprietary Name

CAPSTAR®

## D. Drug Product Established Name

nitenpyram

## E. Pharmacological Category

Antiparasitic

## F. Dosage Form

Tablet

## G. Amount of Active Ingredient

Each tablet contains 11.4 or 57.0 mg nitenpyram.

## H. How Supplied

CAPSTAR® is available in two tablet sizes: 11.4 and 57.0 mg. Each tablet size is available in packages of 6, 12, 30, or 60 tablets.

## I. Dispensing Status

Over the counter (OTC)

**J. Dosage Regimen**

**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 |

***Treatment:***
CAPSTAR® tablets should be administered according to the Recommended Dosage Schedule above. **A second dose should be administered 6 hours after the first.**

***Prevention:***
CAPSTAR® tablets should be administered once daily according to the Recommended Dosage Schedule above. CAPSTAR® tablets must be administered daily to prevent NWS infestations.

**K. Route of Administration**

Oral

**L. Species**

Dogs and Cats

**M. Food and Drug Administration (FDA) Approved Indications**

CAPSTAR® (nitenpyram) tablets (NADA 141-175) 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**.

**N. Emergency Authorized Use**

For the treatment and prevention of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in dogs, puppies, cats and kittens **2 pounds of body weight or greater and 4 weeks of age and older**.

**O. Limitations of Authorized Use**

CAPSTAR® (nitenpyram) tablets are not authorized for use in dogs, puppies, cats and kittens less than 2 pounds of body weight or under 4 weeks of age.

CAPSTAR® (nitenpyram) tablets are authorized for this use only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of CAPSTAR® (nitenpyram) tablets under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or the authorization is revoked sooner.

## II. EFFECTIVENESS

### A. Dosage Characterization

This Emergency Use Authorization does not change the previously approved 0.45 mg/lb (1mg/kg) dose, given orally. The FOI Summary for the original approval of NADA 141-175, dated October 20, 2000, contains dosage characterization information for dogs and cats.

### B. Evidence Supporting Emergency Use Authorization

In accordance with Section 564 of the FD&C Act, the sponsor demonstrated that it is reasonable to believe that CAPSTAR® may be effective for the treatment and prevention of infestations caused by New World screwworm (NWS; *Cochliomyia hominivorax*) larvae (myiasis) in dog, puppies, cats and kittens based on data from published scientific literature. The evidence supporting effectiveness is based on published scientific literature and the mechanism of action of CAPSTAR®. Collectively, the data support that it is reasonable to believe that CAPSTAR® may be effective for the treatment and prevention of infestations caused by NWS (*C. hominivorax*) larvae (myiasis) in dogs, puppies, cats and kittens.

1. Treatment

   a. Correia, T. R., Scott, F. B., Verocai, G. G., Souza, C. P., Fernandes, J. I., Melo, R. M., Vieira, V. P., & Ribeiro, F. A. (2010). Larvicidal efficacy of nitenpyram on the treatment of myiasis caused by *Cochliomyia hominivorax* (Diptera: Calliphoridae) in dogs. *Veterinary Parasitology, 173*(1-2), 169–172.

      The study, conducted in Brazil, evaluated seven laboratory beagles with naturally acquired *C. hominivorax* infestations. The infestations appeared during different seasons of the year. The dogs were 9 months to 6 years of age and weighed 7.9 to 13.2 kg. After diagnosis of myiasis by observation of larvae in a wound, all dogs were administered CAPSTAR® (nitenpyram) tablets orally at the recommended labeled dose for the approved flea indication (range 1.4 to 4.4 mg/kg). A second dose was administered 6 hours after the first dose. The study did not include a control group. Expelled larvae were collected in trays beneath the dogs' kennels for 18 hours after the first dose of CAPSTAR® (15, 30, and 45 minutes, and 1, 2, 3, 4, 6, and 18 hours). After the 18-hour expelled larvae observation period, the remaining larvae were mechanically removed. All expelled and mechanically removed larvae were counted (Table II.1). All larvae were morphologically identified as *C. hominivorax* second and third instar.

**Table II.1. Correia, et al. Total Number of Expelled Larvae, Mean Non-Cumulative and Mean Cumulative Percentage of Expelled Larvae (n = 7)**

| Time Post-Treatment* | Total Number of Larvae Expelled | Mean Non-Cumulative Percentage of Expelled Larvae | Mean Cumulative Percentage of Expelled Larvae |
|---|---|---|---|
| 15 min | 0 | 0 | 0 |
| 30 min | 0 | 0 | 0 |
| 45 min | 1 | 0.1 | 0.1 |
| 1 h | 32 | 4.2 | 4.2 |
| 2 h | 313 | 41.4 | 43.7 |
| 3 h | 144 | 19.1 | 61.9 |
| 4 h | 62 | 8.2 | 69.7 |
| 6 h† | 129 | 17.1 | 86 |
| 18 h | 74 | 9.8 | 95.3 |

*minutes (min), hours (h)
†second dose administered

After the 18-hour expelled larvae observation period and mechanical removal of the remaining larvae, the following parameters were evaluated:

- Larval Expulsion Percentage: ((number of expelled larvae of each animal) / (sum of expelled and mechanically collected larvae of each animal) x 100)
- Percentage of expelled larvae per observational period, considering all animals: ((total of expelled larvae by each time) / (sum of expelled and mechanically collected larvae))

A total of 792 larvae were collected (range 8 to 444). Seven hundred fifty-five of 792 (95.3%) of larvae were expelled (individual expulsion rates ranged from 80 to 100%). Thirty-seven of 792 (4.7%) were removed (individual mechanical removal rates ranged from 0 to 20%).

The larval expulsion percentage was 86% and 95.3%, 6 and 18 hours after the first treatment, respectively. The remaining larvae mechanically removed were dead, demonstrating an overall larvicidal effectiveness of 100%.

No adverse events were reported for the study.

b. Han, H.S., Chen, C., Schievano, C. and Noli, C. (2018), The comparative efficacy of afoxolaner, spinosad, milbemycin, spinosad plus milbemycin, and nitenpyram for the treatment of canine cutaneous myiasis. *Veterinary Dermatology*, 10.1111/vde.12548.

The study evaluated 40 privately-owned dogs with naturally acquired cutaneous myiasis; 8 dogs were treated with CAPSTAR® (nitenpyram) tablets. All screwworms were assumed to be *Chrysomya bezziana* (Old

World screwworm; OWS), but morphological confirmation was not performed to confirm the species. Dogs were randomized to five different treatment groups, eight dogs per group, and dosed orally at doses recommended by the manufacturer for treatment of their approved target parasite species. Dogs were evaluated hourly for 7 hours and again 24 hours post-treatment. Observations were recorded as no observed effect, partial paresis/death of some larvae and its expulsion, and complete death of all larvae. Dogs with live larvae present at 24 hours were then treated with topical organophosphates. All dogs in the CAPSTAR® (nitenpyram) tablets treatment group had complete resolution of their infestation by 6 hours post-treatment. The mean speed of onset was 2.4 hours and the mean time for complete resolution of larvae infestation was 5.4 hours.

No adverse events were reported for the study.

c. de Souza, C. P., Verocai, G. G., & Ramadinha, R. H. (2010). Myiasis caused by the New World screwworm fly *Cochliomyia hominivorax* (Diptera: Calliphoridae) in cats from Brazil: report of five cases. *Journal of feline medicine and surgery, 12*(2), 166–168.

The series case report briefly describes the treatment and outcome of five cats in Brazil with naturally acquired *C. hominivorax* infestations. Three unowned cats presented with massive larval infestations in extensive lesions, including a left humeral fracture, a serious wound on the right front leg and a large wound on the left neck extending to the face. Two client-owned cats, previously treated with cryosurgery, presented with larval infestations in their surgical wounds 18 to 36 days post-surgery. In all cats, debridement of necrotic tissue and mechanical removal of accessible larvae were promptly performed, and CAPSTAR® (nitenpyram) tablets were administered following the recommended labeled dose for the approved flea indication. A few hours after administration, larvae actively left the wound in all cats. Larvae that penetrated deeper into the lesion and were not expelled required mechanical removal. Larvae were classified as third instar *C. hominivorax*. The case reports do not quantify the number of dead or alive, expelled or mechanically removed larvae, and do not provide an effectiveness assessment at any specific time point.

The three unowned cats died 1 to 4 days after treatment. Death of the cats was attributed to the severity of the wounds and massive larval infestations. The client-owned cats were successfully treated.

There are limitations of the data supporting the benefits of CAPSTAR® (nitenpyram) tablets for treatment of infestations caused by NWS in dogs. The Correia et al. study was conducted in a limited population of seven naturally infested laboratory dogs in Brazil and the lack of a control group confounds the ability to define a pure treatment effect. The Han et al. study was conducted with presumptive OWS infestations. The comparability of OWS and NWS is unknown.

The de Souza et al. publication of case reports provides circumstantial support that CAPSTAR® (nitenpyram) tablets may be effective for the treatment of

infestations caused by NWS (*C. hominivorax*) larvae (myiasis) in cats and kittens. The mechanism of action of CAPSTAR® (nitenpyram) tablets is to bind to nicotinic acetylcholine receptors in the postsynaptic membranes and blocks acetylcholine-mediated neuronal transmission causing paralysis and death of the parasite.[1] Based on the de Souza et al. publication, the scientific evidence available to FDA demonstrating effectiveness against *C. hominivorax* myiasis in dogs and puppies treated with CAPSTAR® (nitenpyram) tablets,[2] the mechanism of action of nitenpyram, and the established safety profile in cats, it is reasonable to believe that CAPSTAR® (nitenpyram) tablets may be effective for the treatment of infestations caused by NWS (*C. hominivorax*) larvae (myiasis) in cats and kittens.

2. Prevention

   The lifecycle of the *C. hominivorax* fly can be as short as 21 days. NWS infestations begin when a female fly lays eggs on open wounds or other parts of the body in live, warm-blooded animals. One adult female fly can lay 200 to 300 eggs at a time and up to 3,000 eggs during her 10- to 30-day lifespan. The eggs hatch in 12 to 24 hours depending on environmental conditions. Once hatched, the larvae burrow into the wound to feed on living tissue. The larvae progress through three larval stages (L-1 through L-3) over 5 to 7 days. Once larvae reach the L-3 stage, the larvae fall from the wound and burrow into the ground to pupate, emerging as adult flies in 7 to 54 days depending on temperature and humidity.

   CAPSTAR® does not kill or repel adult flies, prevent adult flies from laying eggs, prevent eggs from hatching, or prevent newly hatched larvae from feeding. Daily administration of CAPSTAR® prevents establishment of NWS infestations by killing newly hatched larvae (L1) within 24 hours of dose administration.

## III. TARGET ANIMAL SAFETY

FDA did not require target animal safety studies for this authorization. The FOI Summary for the original approval of NADA 141-175 dated October 20, 2000, contains a summary of target animal safety studies for dogs and cats.

## IV. HUMAN FOOD SAFETY

This drug is intended for use in dogs and cats. Because this new animal drug is not intended for use in food-producing animals, FDA did not require data pertaining to drug residues in food (i.e., human food safety) for this authorization.

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[1] https://pubchem.ncbi.nlm.nih.gov/compound/3034287

[2] Correia, T. R., Scott, F. B., Verocai, G. G., Souza, C. P., Fernandes, J. I., Melo, R. M., Vieira, V. P., & Ribeiro, F. A. (2010). Larvicidal efficacy of nitenpyram on the treatment of myiasis caused by *Cochliomyia hominivorax* (Diptera: Calliphoridae) in dogs. *Veterinary Parasitology, 173*(1-2), 169-172.

## V. USER SAFETY

The product Fact Sheet contains the following information regarding safety to humans handling, administering, or exposed to CAPSTAR®:

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

## VI. AGENCY CONCLUSIONS

Based on the totality of scientific evidence available to FDA, including data from published literature, it is reasonable to believe that CAPSTAR®, when used as authorized, may be effective for the treatment and prevention of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) in dogs, puppies, cats and kittens 2 pounds of body weight or greater and 4 weeks of age and older, and that the known and potential benefits of CAPSTAR® outweigh the known and potential risks, since NWS infestations can have significant adverse health consequences and can be fatal if left untreated due to the extensive tissue damage caused by *Cochliomyia hominivorax* larvae.

There is no adequate, approved,[3] and available alternative to the product for the treatment and prevention of NWS myiasis in dogs and cats. There are no approved alternatives for the treatment and prevention of NWS myiasis in cats and kittens. There are no adequate, approved, available alternatives for the treatment and prevention of NWS myiasis in dogs and puppies due to the weight and age ranges for dogs, the prescription marketing status, multiple active ingredients, and mechanism of action of the conditionally approved product.

There are no approved alternatives for the treatment and prevention of NWS myiasis in dogs and puppies between 4 and 8 weeks of age or weighing between 2 and 3.3 pounds because the conditionally approved product is indicated for the treatment and prevention of NWS in dogs and puppies at least 8 weeks of age and weighing at least 3.3 pounds.

Additionally, there are no adequate approved OTC products for dogs and puppies, and OTC marketing will allow the product to be available in circumstances where access to a veterinarian is limited.

Furthermore, there are no approved products with a single active ingredient for the treatment and prevention of NWS myiasis in dogs and puppies; CAPSTAR® contains a single active pharmaceutical ingredient, whereas the conditionally approved product contains multiple active ingredients. The presence of multiple active ingredients in the conditionally approved product may increase the likelihood of adverse events in dogs and puppies that have recently been treated with a heartworm preventative or other antiparasitic drug in the same pharmacological class as one of the conditionally approved product's active ingredients. Because CAPSTAR® contains only a single active

[3] "Approved" products include conditionally approved products for purposes of EUAs issued under Section 564 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3.

ingredient that is not in that drug class, its use may minimize the potential for adverse events in these dogs.

Lastly, CAPSTAR® acts through a mechanism of action that is distinct from each of the active ingredients in the conditionally approved product. Because no approved alternative product works through the same mechanism of action as CAPSTAR®, the conditionally approved product is not an adequate therapeutic substitute in circumstances where the CAPSTAR® distinct mechanism of action is clinically relevant.

For additional information on all products authorized or conditionally approved for use to treat and/or prevent New World screwworm, please see FDA's "New World Screwworm: Information for Veterinarians" webpage at https://www.fda.gov/animal-veterinary/safety-health/new-world-screwworm-information-veterinarians.

**A. Duration of Authorization: Revision and Revocation**

This EUA will be effective until revoked under Section 564(g) of the FD&C Act or until the Secretary's declaration of emergency or threat justifying emergency authorized use is terminated (Section 564(f)(1)), with exception for continued use permissible under Section 564(f)(2). FDA may revoke or revise this authorization if emergency use of this animal drug for NWS myiasis is no longer justified, if the product no longer meets the criteria for issuance of an EUA under Section 564(c) of the FD&C Act, or other circumstances make such revocation or revision of the authorization appropriate to protect the public health or safety (Section 564(g)(2) of the FD&C Act).

**B. Marketing Status**

This product is authorized to be marketed OTC because the authorized labeling contains adequate directions for use by laypersons and the conditions of use prescribed on the label are reasonably certain to be followed in practice.