

Approval Date: June 11, 2003

FREEDOM OF INFORMATION SUMMARY

CAPSTAR[®] (nitenpyram) Tablets

Supplemental NADA 141- 175

Novartis Animal Health US, Inc.

Greensboro, NC 27408

This New Animal Drug Application is for the concurrent use of CAPSTAR[®] Tablets with either SENTINEL[®] Flavor Tabs[®] or PROGRAM[®] Flavor Tabs[®] to kill adult fleas and prevent flea eggs from hatching. The effects of SENTINEL[®] Flavor Tabs[®] or PROGRAM[®] Flavor Tabs[®] which control flea populations, and CAPSTAR[®] Tablets, which treat flea infestations, are combined to provide a FLEA MANAGEMENT SYSTEM[™].

1. GENERAL INFORMATION:

- a. File Number: NADA 141-175
- b. Sponsor: Novartis Animal Health US, Inc.
3200 Northline Ave., Suite 300
Greensboro, NC 27408
Drug Labeler Code: 058198
- c. Established Name: Nitenpyram
- d. Proprietary Name: CAPSTAR[®] Tablets
- e. Dosage Form: Oral tablets
- f. How Supplied: CAPSTAR[®] Tablets are available in two tablet sizes (see Dosage section) formulated according to the weight of the dog or cat. Each tablet size is available in color-coded packages containing six tablets.
- g. How Dispensed: OTC
- h. Amount of Active Ingredients: Refer to the dosage section.
- i. Route of Administration: Oral
- j. Species/Class: Dogs and Cats

k. Recommended Dosage:

CAPSTAR[®] Tablets should be administered according to the Recommended Dosage Schedule below. **Weigh your pet prior to administration to ensure proper dosage.** Do not administer to pets under 2 pounds. A single dose of CAPSTAR[®] 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.

Recommended Dosage Schedule

Species	Body Weight	Dose	Nitenpyram mg/Tablet
Dog or Cat	2 - 25 lbs	One tablet	11.4 mg
Dog	25.1 - 125 lbs	One tablet	57 mg

The dosage schedule for the concurrent use of CAPSTAR[®] Tablets and SENTINEL[®] Flavor Tabs[®] is addressed in NADA 141-204.

The dosage schedule for the concurrent use of CAPSTAR[®] Tablets and PROGRAM[®] Flavor Tabs[®] is addressed in NADA 141-205.

l. Pharmacological Category:

Nitenpyram is a flea adulticide.

m. Indications:

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

n. Effect of Supplement:

Approval of this supplemental NADA will change the labeling for NADA 141-175.

1. The text in the “Indications” section is changed to include the words “kill adult fleas.” The section will now read: “CAPSTAR[®] Tablets kill adult fleas and are indicated for the treatment of flea infestations on dogs, puppies, cats and kittens 4 weeks of age and older and 2 pounds of body weight or greater.” This change makes the labeling more consistent with labeling for other approved products that kill adult fleas.
2. There are some minor revisions to clarify the currently approved text in the package insert and the unit dose cartons.
3. The package insert is revised to include reference to the concurrent use of PROGRAM[®] (lufenuron) Flavor Tabs[®] (NADA 141-035) to kill adult fleas and prevent flea eggs from hatching. The information supporting approval for this concurrent use is documented in NADA 141-205.
4. The package insert is revised to refer the reader to a veterinarian for information about the concurrent use of SENTINEL[®] (milbemycin oxime/lufenuron) Flavor Tabs[®] (NADA 141-084), to kill adult fleas and prevent flea eggs from hatching. SENTINEL[®] Flavor Tabs[®] are a prescription product. The information supporting approval for this concurrent use is documented in NADA 141-204.
5. The unit dose cartons are revised to refer to concurrent use with PROGRAM[®] (lufenuron) Flavor Tabs[®].
6. Each unit dose carton will contain an additional “FLEA MANAGEMENT SYSTEM[™]” package insert that provides specific information for using CAPSTAR[®] Tablets with PROGRAM[®] (lufenuron) Flavor Tabs[®].

2. EFFECTIVENESS:

- a. For information about the effectiveness of CAPSTAR[®] Tablets please refer to the FOI summary for the original approval dated October 20, 2000 (A-0000).
- b. For information about the effectiveness of the concurrent use of CAPSTAR[®] Tablets with PROGRAM[®] Flavor Tabs[®] please refer to the FOI summary for NADA 141-205.
- c. For information about the effectiveness of the concurrent use of CAPSTAR[®] Tablets with SENTINEL[®] Flavor Tabs[®] please refer to the FOI summary for NADA 141-204.

3. TARGET ANIMAL SAFETY:

- a. For information about the safety of CAPSTAR[®] Tablets please refer to the FOI summary for the original approval dated October 20, 2000 (A-0000).
- b. For information about the safety of the concurrent use of CAPSTAR[®] Tablets with PROGRAM[®] Flavor Tabs[®] please refer to the FOI summary for NADA 141-205.
- c. For information about the safety of the concurrent use of CAPSTAR[®] Tablets with SENTINEL[®] Flavor Tabs[®] please refer to the FOI summary for NADA 141-204.

4. HUMAN SAFETY:

This drug is intended for use in dogs and cats, which are non-food animals. Because this new animal drug is not intended for use in food producing animals, data on human safety pertaining to drug residues in food were not required for approval of this NADA.

Human Warnings are provided on the product label as follows: “Not for human use. Keep this and all drugs out of the reach of children.”

5. AGENCY CONCLUSIONS:

The data in support of this supplemental NADA satisfy the requirements of Section 512 of the Federal Food, Drug, and Cosmetic Act and 21 CFR Part 514 of the implementing regulations. The data demonstrate that CAPSTAR[®] Tablets, when administered in accordance with the directions provided by the revised labeling, are safe and effective for the treatment of flea infestations on dogs, puppies, cats, and kittens.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act, this approval qualifies for THREE years of marketing exclusivity beginning on the date of the approval. The three years of marketing exclusivity applies only to the concurrent use with SENTINEL[®] (milbemycin oxime/lufenuron) Flavor Tabs[®] and concurrent use with PROGRAM[®] (lufenuron) Flavor Tabs[®] for which this supplement is approved.

According to the Center's supplemental approval policy (21 CFR 514.106), this is a Category II change. The approval of this change is not expected to have any adverse effect on the safety or effectiveness of this new animal drug. Accordingly, this approval did not require a reevaluation of the safety and effectiveness data in the parent application.

CAPSTAR[®] is under the following U.S. patent number: 5,750,548
Date of Expiration: April 29, 2016.

6. ***ATTACHMENTS:***

Facsimile Labeling is attached as indicated below.

- a. CAPSTAR[®] Package Insert
- b. Unit Dose Cartons - 11.4 mg, 57 mg