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CAPSTAR®

Novartis

### **(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 Ingredients**

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.**

<b>Recommended Dosage Schedule</b>			
<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

\*Please see separate insert in this package for concurrent dosing of CAPSTAR Tablets and PROGRAM<sup>®</sup> (lufenuron) Flavor Tabs<sup>®</sup>.

### **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. 2010):**

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 suspected adverse drug events, contact Novartis Animal Health at 1-800-637-0281 or the FDA at 1-800-FDA-VETS or: <http://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm055305.htm>

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

<http://www.fda.gov/AnimalVeterinary/SafetyHealth/ProductSafetyInformation/ucm055394.htm>

For technical assistance call Novartis Animal Health at 1-800-637-0281

### **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**

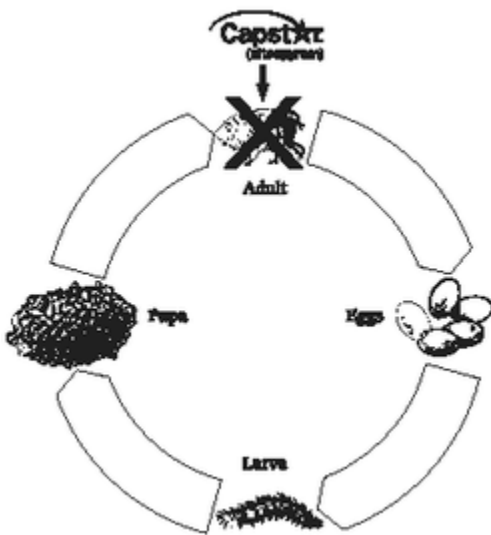
In addition to the common nuisance irritations associated with infestations, fleas can be responsible for skin conditions in your pet such as flea allergy dermatitis (FAD) in the dog and miliary dermatitis in the cat. Also, fleas transmit other parasites, including tapeworms. The control of flea infestations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

In addition to killing adult fleas with CAPSTAR, you can treat your pet with an insect development inhibitor like PROGRAM Flavor Tabs to prevent and control flea populations. Please see the separate PROGRAM Flavor Tabs/CAPSTAR Tablets FLEA MANAGEMENT SYSTEM insert included in this package for information on how to use these two products together to kill adult fleas and prevent flea eggs from hatching. For information on how to use SENTINEL<sup>®</sup> (milbemycin oxime/lufenuron) Flavor Tabs<sup>®</sup> (for dogs only) with CAPSTAR Tablets, see your veterinarian.

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 1-800-332-2761

For technical assistance or to report a suspected adverse event please call 1-800-637-0281

Visit our web site at [www.capstarpet.com](http://www.capstarpet.com)

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***PROGRAM***<sup>®</sup> (*LUFENURON*) *Flavor Tabs*<sup>®</sup> / **Capstar**<sup>®</sup> (**nitenpyram**) **FLEA MANAGEMENT SYSTEM**

Supplemental Product Information

### **Information for Dosing Cats**

This insert describes the concurrent use of **PROGRAM**<sup>®</sup> (lufenuron) *Flavor Tabs*<sup>®</sup> and **CAPSTAR**<sup>®</sup> (nitenpyram) Tablets for the management of fleas on cats and kittens.

**Please read the insert contained in each package for complete information on the individual products prior to dosing.**

### **Warnings**

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

### **Directions**

In cats and kittens the concurrent use of **PROGRAM** *Flavor Tabs* and **CAPSTAR** Tablets is indicated to kill adult fleas and prevent eggs from hatching. The effects of **PROGRAM** *Flavor Tabs*, which control flea

populations, and CAPSTAR Tablets, which treat flea infestations, are combined to provide a FLEA MANAGEMENT SYSTEM.

### Step 1: Prevention and Control

Give PROGRAM Flavor Tabs once per month to control flea populations. PROGRAM Flavor Tabs contain lufenuron. Lufenuron controls flea populations by preventing the development of flea eggs and does not kill adult fleas. If a cat currently has a flea infestation, more rapid relief can be accomplished by adding CAPSTAR to the treatment as follows.

### Step 2: Kill Adult Fleas

If your pet currently has a flea infestation, use CAPSTAR Tablets to kill adult fleas. CAPSTAR Tablets contain nitenpyram and are effective for the treatment of flea infestations. Nitenpyram starts killing adult fleas within 30 minutes of administration.

- Administer CAPSTAR Tablets once per week until adult fleas are no longer observed.
- For a *severe* flea infestation, administer CAPSTAR Tablets twice per week until adult fleas are no longer observed.
- Additional CAPSTAR Tablets may be administered as needed to kill the occasional adult flea picked up from infested environments.
- It is important to treat all cats and dogs (see below) in the household. Fleas can reproduce on untreated pets and allow infestations to persist.

### Dosage

The combination of PROGRAM Flavor Tabs and CAPSTAR Tablets should be administered according to the following schedule. **Weigh the cat prior to administration to ensure proper dosage. Do not administer to cats under 2 pounds or less than 4 weeks of age.**

**TO ENSURE ADEQUATE ABSORPTION, ALWAYS ADMINISTER PROGRAM FLAVOR TABS IN CONJUNCTION WITH A NORMAL MEAL (see package insert for PROGRAM Flavor Tabs for details).**

Recommended Dosage Schedule			
Body Weight	Dose	CAPSTAR Once or twice weekly* (Nitenpyram per tablet)	PROGRAM Flavor Tabs once per month (Lufenuron per tablet)
2 to 6 lbs.	One tablet	11.4 mg	90 mg
7 to 15 lbs.	One tablet	11.4 mg	204.9 mg
16 to 25 lbs.	One tablet	11.4 mg	**

\*If adult fleas are seen

\*\* *Cats over 15 lbs. are provided the appropriate combination of PROGRAM Flavor Tabs.*

### Adverse Reactions

**The following adverse reactions have been reported in cats after giving PROGRAM Flavor Tabs: vomiting, depression/lethargy, anorexia (loss of appetite), diarrhea, hyperactivity, dyspnea (labored breathing), pruritus (itchy skin), and skin eruptions (rash).**

**The following adverse reactions have been reported in cats after giving CAPSTAR: hyperactivity, panting, lethargy, itching, vocalization, vomiting, fever, decreased appetite, nervousness, diarrhea, difficulty breathing, salivation, incoordination, seizures, pupil dilation, increased heart rate, and trembling.**

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 suspected adverse drug events and/or for a complete listing of adverse reactions for lufenuron and nitenpyram reported to the FDA CVM, please refer to the insert contained within the CAPSTAR package for contact information.

### **Other Information**

The safety of the concurrent use of PROGRAM Flavor Tabs and CAPSTAR Tablets has not been evaluated in kittens less than 7 months of age.

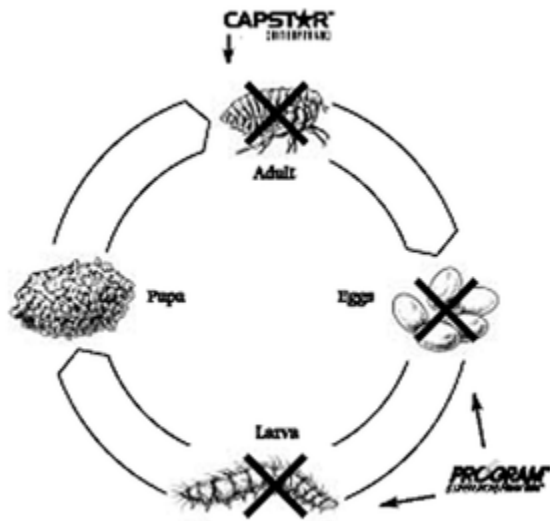
### **Flea Infestations on Cats**

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

PROGRAM Flavor Tabs break the flea life cycle by inhibiting egg development. CAPSTAR Tablets rapidly kill adult fleas on the cat. The concurrent use of these two products provides an effective flea management system.

The following diagram illustrates the flea's life cycle and where the combination of PROGRAM Flavor Tabs and CAPSTAR Tablets work:

### **Life Cycle of the Flea**



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 the pet and subsequently lay eggs, which drop off the pet's coat. Within days, larvae hatch from the eggs and live undetected in the pet's surroundings, such as the carpet and bedding. Flea larvae spin a cocoon, and, when appropriately stimulated, a young adult flea emerges and jumps onto the pet to continue the life cycle.

After reading this insert, if you have any questions about the concurrent use of PROGRAM Flavor Tabs and CAPSTAR Tablets in your cats, please call Novartis Animal Health US, Inc. Veterinary Product Support at 1-800-637-0281.

### Storage Conditions

Store PROGRAM Flavor Tabs and CAPSTAR as described on the individual product inserts.

Questions? Comments?

Please Call 1-800-332-2761

For technical assistance or to report a suspected adverse event please call 1-800-637-0281

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## Information for Dosing Dogs

This insert describes the concurrent use of PROGRAM<sup>®</sup> (lufenuron) Flavor Tabs<sup>®</sup> and CAPSTAR<sup>®</sup> (nitenpyram) Tablets for the management of fleas on dogs and puppies.

**Please read the insert contained in each package for complete information on the individual products prior to dosing.**

### Warnings

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

### Directions

In dogs and puppies the concurrent use of PROGRAM Flavor Tabs and CAPSTAR Tablets is indicated to kill adult fleas and prevent eggs from hatching. The effects of PROGRAM Flavor Tabs, which prevent and control flea populations, and CAPSTAR Tablets, which treat flea infestations, are combined to provide a FLEA MANAGEMENT SYSTEM.

#### Step 1: Prevention and Control

Give PROGRAM Flavor Tabs once per month to prevent and control flea populations. PROGRAM Flavor Tabs contain lufenuron. Lufenuron controls flea populations by preventing the development of flea eggs and does not kill adult fleas. If a dog currently has a flea infestation, more rapid relief can be accomplished by adding CAPSTAR to the treatment as follows.

#### Step 2: Kill Adult Fleas

If your pet currently has a flea infestation, use CAPSTAR Tablets to kill adult fleas. CAPSTAR Tablets contain nitenpyram and are effective for the treatment of flea infestations. Nitenpyram starts killing adult fleas within 30 minutes of administration.

- Administer CAPSTAR Tablets once per week until adult fleas are no longer observed.
- For a *severe* flea infestation, administer CAPSTAR Tablets twice per week until adult fleas are no longer observed.
- Additional CAPSTAR Tablets may be administered as needed to kill the occasional adult flea picked up from infested environments.
- It is important to treat all dogs and cats (see below) in the household. Fleas can reproduce on untreated pets and allow infestations to persist.

### Dosage

The combination of PROGRAM Flavor Tabs and CAPSTAR Tablets should be administered according to the following schedule. **Weigh the dog prior to administration to ensure proper dosage. Do not administer to dogs under 2 pounds or less than 4 weeks of age.**



**TO ENSURE ADEQUATE ABSORPTION, ALWAYS ADMINISTER PROGRAM FLAVOR TABS IN CONJUNCTION WITH A NORMAL MEAL (see package insert for PROGRAM Flavor Tabs for details).**

<b>Recommended Dosage Schedule</b>			
<b>Body Weight</b>	<b>Dose</b>	<b>CAPSTAR Once or twice weekly* (Nitenpyram per tablet)</b>	<b>PROGRAM Flavor Tabs once per month (Lufenuron per tablet)</b>
2 to 10 lbs.	One tablet	11.4 mg	45 mg
11 to 20 lbs.	One tablet	11.4 mg	90 mg
21 to 25 lbs.	One tablet	11.4 mg	204.9 mg
26 to 45 lbs.	One tablet	57 mg	204.9 mg
46 to 90 lbs.	One tablet	57 mg	409.8 mg
91 to 125 lbs.	One tablet	57 mg	**

\*If adult fleas are seen

\*\* *Dogs over 90 lbs. are provided the appropriate combination of PROGRAM Flavor Tabs.*

### **Adverse Reactions**

**The following adverse reactions have been reported in dogs after giving PROGRAM Flavor Tabs: vomiting, depression/lethargy, pruritus (itchy, scratchy skin), urticaria (wheals, hives), diarrhea, anorexia (loss of appetite), and skin congestion (red skin).**

**The following adverse reactions have been reported in dogs after giving CAPSTAR: 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 suspected adverse drug events and/or for a complete listing of adverse reactions for lufenuron and nitenpyram reported to the FDA CVM, please refer to the insert contained within the CAPSTAR package for contact information.

### **Other Information**

The safety of the concurrent use of lufenuron, the active ingredient in PROGRAM Flavor Tabs, and CAPSTAR Tablets has not been evaluated in puppies less than 11 weeks old.

### **Flea Infestations on Dogs**

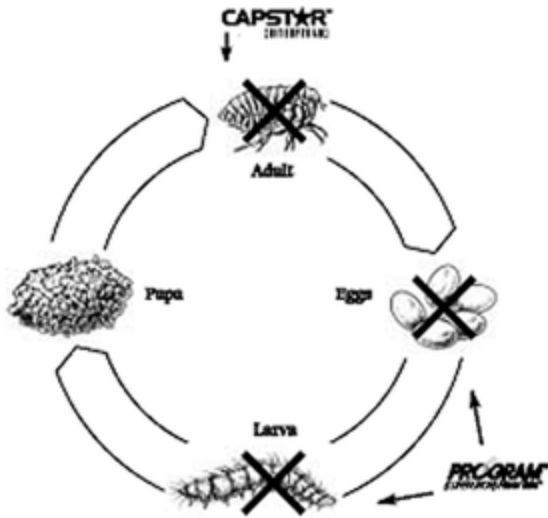
In addition to the common nuisance irritations associated with infestations, fleas can be responsible for skin conditions in the dog such as flea allergy dermatitis. Fleas also transmit other parasites, including tapeworms.

The control of flea infestations is important to the pet's health and reduces the problems associated with these parasites.

PROGRAM Flavor Tabs break the flea life cycle by inhibiting egg development. CAPSTAR Tablets kill adult fleas on the dog. The concurrent use of these two products provides an effective flea management system.

The following diagram illustrates the flea's life cycle and where the combination of PROGRAM Flavor Tabs and CAPSTAR Tablets work:

### Life Cycle of the Flea



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 the pet and subsequently lay eggs, which drop off the pet's coat. Within days, larvae hatch from the eggs and live undetected in the pet's surroundings, such as the carpet and bedding. Flea larvae spin a cocoon, and, when appropriately stimulated, a young adult flea emerges and jumps onto the pet to continue the life cycle.

After reading this insert, if you have any questions about the concurrent use of PROGRAM Flavor Tabs and CAPSTAR Tablets in your dogs, please call Novartis Animal Health US, Inc. Veterinary Product Support at 1-800-637-0281.

### Storage Conditions

Store PROGRAM Flavor Tabs and CAPSTAR as described on the individual product inserts.

Questions? Comments?

Please Call 1-800-332-2761

For technical assistance or to report a suspected adverse event please call 1-800-637-0281

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**NAC No.:** 11310108