

CAPSTAR- nitenpyram tablet
Elanco US Inc.

Caps tar™
(nitenpyram)

PA101598X

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.**

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 1-888-545-5973. 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 Elanco US Inc. at 1-888-545-5973

Other Information

CAPSTAR (nitenpyram) 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

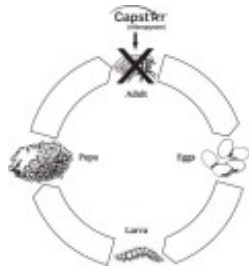
In addition to the common nuisance irritations associated with infestations, fleas can be responsible for skin conditions in your pet such as flea allergy dermatitis (FAD) in the dog and miliary dermatitis in the cat. Also, fleas transmit other parasites, including tapeworms. The control of flea infestations 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 1-888-545-5973

For technical assistance or to report a suspected adverse event please call 1-888-545-5973

Visit our web site at www.capstarpet.com

Manufactured for: Elanco US Inc.
Greenfield, IN 46140, USA

Approved by FDA under NADA # 141-175

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Revision date: January 2020

Elanco™

Principal Display Panel - 11.4 mg Carton Label

Caps tar™

(nitenpyram)

11.4 mg

6 Tablets

(11.4 mg nitenpyram each)

For Dogs and Cats

2–25 lbs.

For treatment of flea infestations on dogs and cats.

For Oral Use.

NADA #141-175
 Approved by FDA
 Product # 604152
Elanco



Principal Display Panel - 11.4 mg Carton Label
Capstar™

(nitenpyram)

11.4 mg

60 Tablets

(11.4 mg nitenpyram each)

For Dogs and Cats

2–25 lbs.

For treatment of flea infestations on dogs and cats.

For Oral Use.

NADA #141-175

Approved by FDA

Product # 604152

Elanco



Capstar[™]
(nitenpyram)

.....

For treatment of
dogs and cats
1 kg to 11 kg.
.....
Pour le traitement
des chiens et
chats de 1 à 11 kg.
.....


For treatment of dogs and cats 1 kg to 11 kg.
Pour le traitement des chiens et chats de 1 à 11 kg.

Elanco

Capstar[™]
(nitenpyram)
FOR VETERINARY USE ONLY
POUR USAGE VÉTÉRINAIRE SEULEMENT

For treatment of dogs and cats 1 kg to 11 kg.
Pour le traitement des chiens et chats de 1 à 11 kg.



Capstar[™]
(nitenpyram)

Capstar[™]
(nitenpyram)

Elanco Canada Limited
150 Research Lane, Suite 120
Guelph, Ontario N1G 4T2

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9H100002048

Elanco

Principal Display Panel - 57 mg Carton Label

Caps tar™

(nitenpyram)

57.0 mg

6 Tablets

(57.0 mg nitenpyram each)

For Dogs Over 25 lbs.

For treatment of flea infestations on dogs.

For Oral Use.

NADA #141-175

Approved by FDA

Product # 604154

Elanco



Principal Display Panel - 57 mg Box Label

**Capstar™
(nitenpyram)**

60 Tablets

(57.0 mg nitenpyram each)

For Oral Use.

For Dogs Over 25 lbs.

For treatment of flea infestations on dogs.

Elanco



Capstar[®]

(nitenpyram)

60 Tablets
(57.0 mg
nitenpyram each)



For Dogs
Over 25 lbs.

For treatment
of flea
infestations
on dogs.

For Oral Use.

[NADA #141-175
Approved by FDA]

Product # 604154

60 Tablets
(57.0 mg
nitenpyram each)

For Oral Use.

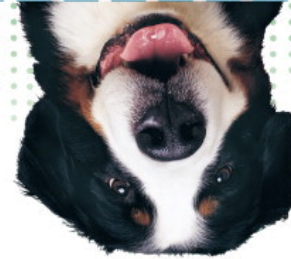


For Dogs
Over 25 lbs.

For treatment
of flea
infestations
on dogs.

Capstar[®]
(nitenpyram)

Elanco



57.0 mg

Capstar[®]
(nitenpyram)

Capstar[®]

(nitenpyram)



Begins
working
within
30 minutes

604154
CAPSTAR 57.0 mg

Net Contents:
60 Tablets of 57.0 mg
nitenpyram each

Manufactured for:
Elanco US Inc.
Greenfield, IN 46140, USA
Product of Switzerland

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Bristol-Myers Squibb and Company, its subsidiaries or affiliates.

SH100007AMB 916576

Store at controlled
room temperature,
between 59° and 77°F
(15°-25° C).

www.capstarpet.com

Elanco

Principal Display Panel - 11.4 mg Cat and Dog Box Label

CAPSTAR™

(nitenpyram)

11.4 mg

Treatment of flea
infestations on cats
and dogs

For oral use

60 tablets

(11.4 mg nitenpyram each)

Begins
working within

30 minutes



CAPSTAR™
(nitenpyram)

Treatment of flea infestations on cats and dogs

For oral use
60 tablets
(11.4 mg nitenpyram each)

Begins working within **30 minutes**



Product # 604153
CAPSTAR 11.4 mg
60 tablets of 11.4 mg nitenpyram each

Net Contents:

Manufactured for: Elanco US Inc.
Greenville, IN 46160, USA
Product of Switzerland

Store at controlled room temperature, between 59° and 77°F (15°-25°C).

www.capstarpet.com
For technical assistance call 1-888-545-5970

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CAPSTAR™
(nitenpyram)
11.4 mg

Treatment of flea infestations on cats and dogs

For oral use
60 tablets
(11.4 mg nitenpyram each)

Begins working within **30 minutes**

CAPSTAR™
(nitenpyram)

Principal Display Panel - 11.4 mg Dog Box Label

CAPSTAR™

(nitenpyram)

11.4 mg

Treatment of flea

infestations on dogs

For oral use

Begins working
within 30 minutes

For dogs **2-25 lbs** | **60 tablets**

[NADA #141-175 Approved by FDA]

Elanco™



Principal Display Panel - 11.4 mg Dog Carton Label

CAPSTAR™

(nitenpyram)

11.4 mg

Treatment of flea
infestations on dogs

For oral use

Beings working
within 30 minutes

For dogs 2-25 lbs | 6 tablets (11.4 mg each)

Keep this and all drugs out of reach of children

[NADA #141-174 Approved by FDA]

Elanco™

CAPSTAR™ (nitenpyram)

11.4 mg



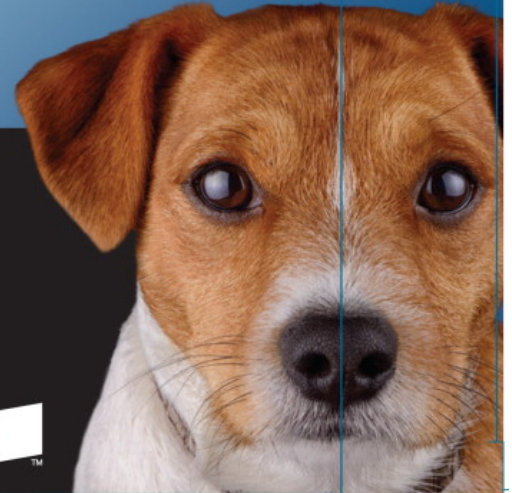
Treatment of flea infestations on dogs



For oral use



Begins working within 30 minutes



For dogs 2-25 lbs | 6 tablets (11.4 mg each)

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

Elanco™



Begins working within 30 minutes

For dogs 2-25 lbs

CAPSTAR™
(nitenpyram)

CAPSTAR™
(nitenpyram)



Product # 604152



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Product of Switzerland. www.capstarpet.com
Manufactured for: Elanco US Inc. Greenfield, IN 46140, USA
Between 59° and 77°F (15°-25°C).

Please call 1-888-545-5973. Store at controlled room temperature.

QUESTIONS or COMMENTS?

- CAPSTAR kills adult fleas that cause flea allergy dermatitis (FAD).
- CAPSTAR can be used with Iufenuron to provide a FLEA MANAGEMENT SYSTEM. The two products, when used together, kill adult fleas and prevent flea eggs from hatching.
- CAPSTAR can be used with Iufenuron to provide a FLEA MANAGEMENT SYSTEM. The two products, against 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:

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. Please refer to the package insert for complete information.

DIRECTIONS:

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

WARNINGS:



Begins working within 30 minutes

For dogs 2-25 lbs

CAPSTAR™
(nitenpyram)

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Principal Display Panel - 11.4 mg Cat Box Label
CAPSTAR™
(nitenpyram)

11.4 mg

Treatment of flea infestations on cats

For oral use

Begins working within 30 minutes

For cats **2-25 lbs** | **60 tablets**

[NADA #141-175 Approved by FDA]

Elanco™



Principal Display Panel - 11.4 mg Cat Carton Label

CAPSTAR™

(nitenpyram)

11.4 mg

Treatment of flea infestations on cats

For oral use

Beings working
within 30 minutes

For cats **2-25 lbs | 6 tablets (11.4 mg each)**

Keep this and all drugs out of reach of children

[NADA #141-174 Approved by FDA]

Elanco™

CAPSTAR™ (nitenpyram)

11.4 mg



Treatment of flea infestations on cats



For oral use

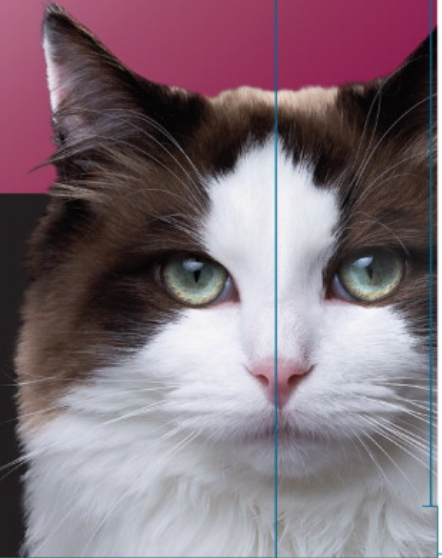


Begins working within 30 minutes

For cats **2-25 lbs** | **6 tablets (11.4 mg each)**

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

Elanco™



Begins working within 30 minutes

For cats **2-25 lbs**

CAPSTAR™
(nitenpyram)

Elanco™

Product # 604152

IMPRINT HERE



Please call 1-888-545-5973. Store at controlled room temperature, between 59° and 79°F (15°-25°C).
Manufactured for: Elanco US Inc, Greenfield, IN 46140, USA
Product of Switzerland. www.capstarpet.com

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 and prevent flea eggs from hatching.
- CAPSTAR can be used with lufenuron to provide a FLEA MANAGEMENT SYSTEM. The two products, against adult fleas on cats within 6 hours.
- Begins working within 30 minutes. In studies, CAPSTAR achieved greater than 90% effectiveness against adult fleas on cats within 6 hours.
- CAPSTAR is safe for use in cats and kittens **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 cats.

OTHER INFORMATION:

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. Please refer to the package insert for complete information.

DIRECTIONS:

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

WARNINGS:

CAPSTAR™
(nitenpyram)

LOT
EXP



Begins working within 30 minutes

For cats **2-25 lbs**

CAPSTAR™
(nitenpyram)

Principal Display Panel - 57.0 mg Dog Box Label

CAPSTAR™

(nitenpyram)

57.0 mg

Treatment of flea
infestations on dogs

For oral use

Begins working
within 30 minutes

for dogs **over 25lbs | 60 tablets**

[NADA #141-175 Approved by FDA]

Elanco™



Product of Switzerland
 Manufactured for: Elanco US Inc.
 Greentield, IN 46160, USA
 Net Contents:
 CAPSTAR 57.0 mg
 60 tablets of 57.0 mg nitenpyram each

Store at controlled room temperature,
 between 59° and 77°F (15°-25°C).

www.capstarpet.com
 For technical assistance call
 1-888-545-5973



Principal Display Panel - 57.0 mg Dog Box Label

CAPSTAR™

(nitenpyram)

57.0 mg

Treatment of

flea infestations
on dogs

For oral use

60 tablets

(57.0 mg nitenpyram each)

Begins
working within
30 minutes



Principal Display Panel - 57.0 mg Dog Carton Label

CAPSTAR™

(nitenpyram)

57.0 mg

Treatment of flea
infestations on cats

For oral use

Beings working
within 30 minutes

For dogs **over 25 lbs | 6 tablets (57.0 mg each)**

Keep this and all drugs out of reach of children

[NADA #141-174 Approved by FDA]

Elanco™

CAPSTAR™ (nitenpyram)

57.0 mg



Treatment of flea infestations on dogs



For oral use



Begins working within 30 minutes

For dogs **over 25 lbs** | **6 tablets (57.0 mg each)**

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

Elanco™



Begins working within 30 minutes

For dogs **over 25 lbs**

CAPSTAR™
(nitenpyram)

CAPSTAR™
(nitenpyram)

Elanco™

Product # 604154



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Please call 1-888-545-5973. Store at controlled room temperature, between 59° and 77°F (15°-25°C).
Manufactured for: Elanco US Inc, Greenfield, IN 46140, USA
Product of Switzerland. www.capstarpet.com

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 and prevent flea eggs from hatching.
- CAPSTAR can be used with IUFENURON to provide a FLEA MANAGEMENT SYSTEM. The two products, against 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:

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. Please refer to the package insert for complete information.

DIRECTIONS:

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

WARNINGS:

LOT
EXP



Begins working within 30 minutes

For dogs **over 25 lbs**

CAPSTAR™
(nitenpyram)

CAPSTAR

nitenpyram tablet

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:58 198-4920
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: 70097M6B30)	

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:58 198-4920-1	1 in 1 BOX		
1		6 in 1 BLISTER PACK		
2	NDC:58 198-4920-5	10 in 1 CARTON		
2		6 in 1 BOX		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA141175	10/20/2000	

CAPSTAR

nitenpyram tablet

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:58 198-4925
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Nitenpyram (UNII: 3A837VZ8 1Y) (Nitenpyram - UNII:3A837VZ8 1Y)	Nitenpyram	57 mg

Inactive Ingredients

Ingredient Name	Strength
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D6 1U)	
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:58 198 -4925-1	1 in 1 BOX		
1		6 in 1 BLISTER PACK		
2	NDC:58 198 -4925-5	10 in 1 CARTON		
2		6 in 1 BOX		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA141175	10/20/2000	

Labeler - Elanco US Inc. (966985624)**Establishment**

Name	Address	ID/FEI	Business Operations
Elanco France SAS		736833104	ANALYSIS, LABEL, MANUFACTURE, PACK

Revised: 4/2020

Elanco US Inc.