

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

NATURE/TYPE: Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CAPSTAR 57 mg, tablets for large dogs
Nitenpyram

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Nitenpyram, 57 mg / tablet

3. PHARMACEUTICAL FORM

Tablet

4. PACKAGE SIZE

1 tablet
6 tablets
60 tablets

5. TARGET SPECIES

Dog

6. INDICATION(S)

Treatment of flea infestations (*C. felis*) on dogs.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 25° C

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet before use.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only - to be supplied only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd
Form 2, Bartley Way
Bartley Wood Business Park
Hook, RG27 9XA

16. MARKETING AUTHORISATION NUMBER(S)

Vm 00879/4082

17. MANUFACTURER’S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

NATURE/TYPE: Blister foil

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CAPSTAR 57 mg, tablets for large dogs

Nitenpyram

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Lot {number}

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PACKAGE LEAFLET

CAPSTAR 57 mg, tablets for large dogs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:

Elanco Europe Ltd
Form 2, Bartley Way
Bartley Wood Business Park
Hook, RG27 9XA

Manufacturer responsible for batch release:

Elanco France S.A.S., 26 Rue de la Chapelle, F-68330 Huingue, France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

CAPSTAR 57 mg, tablets for large dogs

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Nitenpyram, 57 mg/tablet

4. INDICATION(S)

Treatment of flea infestations (*C. felis*) on dogs.

5. CONTRAINDICATIONS

None

6. ADVERSE REACTIONS

For the first hour after administration, the pet may scratch more than normal. This effect is caused by the fleas reacting to the product. In very rare cases this may present as transient signs of hyperactivity, panting, vocalisation, and excessive grooming/licking.

Transient neurological signs such as muscle tremors, ataxia, and convulsions have also been reported in very rare occasions.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dog.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

One CAPSTAR 57 mg tablet should be given to dogs weighing 11.1 kg to 57.0 kg and two tablets for dogs weighing over 57 kg when a flea infestation is detected. The frequency of treatment depends on the degree of infestation. In the case of a severe flea infestation, it may be necessary to treat the animals every day or every other day, until the flea infestation is controlled. Treatment may be resumed if fleas reappear. No more than one treatment should be given per day.

CAPSTAR does not have persistent activity. To prevent re-infestation, a suitable treatment to control immature stages of the flea life cycle is recommended. The veterinary surgeon should establish an appropriate treatment regime.

9. ADVICE ON CORRECT ADMINISTRATION

Fleas can be detected by parting the coat of the animal to examine the skin or by combing its coat with a fine metal comb. Frequent scratching or excessive grooming can also be signs of flea infestation.

Tablets should be given directly into the mouth, with or without food. In order to improve palatability, tablets can be disguised in a small quantity of food immediately prior to administration.

10. WITHDRAWAL PERIOD

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children. Do not store above 25 °C. Do not use after the expiry date stated on the blister after EXP.

12. SPECIAL WARNING(S)

Nitenpyram can be used during pregnancy and lactation. Do not use on dogs weighing less than 11 kg.
as this group of animals was not studied.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

September 2020

15. OTHER INFORMATION

Effects on fleas (*Ctenocephalides felis*) may be seen as soon as 15-30 minutes after administration of the product to the host animal. Between 95% and 100% of the fleas are killed within the first 6 hours and 100% of the fleas are killed within 24 hours with no residual activity.

Nitenpyram is well-tolerated by cats and dogs. Overdoses up to 50 mg/kg in cats and up to 70 mg/kg in dogs were without symptoms.

Not all pack sizes may be marketed.

A handwritten signature in black ink, consisting of several vertical strokes followed by a horizontal line that curves upwards to the right.

Approved 09 September 2020