PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Carton box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Capstar 57 mg tablets

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Nitenpyram, 57 mg / tablet

3. PACKAGE SIZE

1 tablet
6 tablets
60 tablets

4. TARGET SPECIES

Dog

5. INDICATION(S)

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

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. mm/yyyy

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.

Keep the blister in the outer packaging.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

Elanco logo

14. MARKETING AUTHORISATION NUMBERS

Vm 00879/5024

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS
{polyamide/aluminium/PVC-aluminium blister}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Capstar

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

Nitenpyram 57 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

5. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Capstar 57 mg tablets for large dogs

2. COMPOSITION

One tablet contains:

Active substance: Nitenpyram 57 mg

Excipient:

Qualitative composition of excipients and other constituents
Microcrystalline cellulose
Maize starch
Lactose monohydrate
Anhydrous silica
Magnesium stearate

White to light yellow, round, biconvex tablets, with bevelled edges, imprinted on one side with “HIH”, on the other side with “CG”.

3. TARGET SPECIES

Dogs.

4. INDICATIONS FOR USE

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

5. CONTRAINDICATIONS

None

6. SPECIAL WARNING(S)

Special warnings:
Do not use on animals less than 4 weeks old or dogs weighing less than 11 kg.

Pregnancy and lactation:
Can be used during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:
None known. No adverse drug reactions were seen in clinical studies when nitenpyram was administered with other veterinary medicinal products including commonly used flea products, anthelmintics, vaccines or antibiotics.

Overdose:
Nitenpyram is well-tolerated by the target species. Overdoses up to 50 mg/kg in cats and up to 70 mg/kg in dogs were asymptomatic.

Side-effects such as salivation, vomiting, soft stools, seizures, or decreased activity are observed at higher dosages and their seriousness increases as dosages increase. Symptoms disappear quickly and recovery is complete by 24 hours after overdosing because of the rapid elimination of nitenpyram. During 6 months of daily dosing in cats and dogs no clinically significant treatment-related side effects were observed.

7. ADVERSE EVENTS

Dogs:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Excessive chewing, licking and/or grooming[1], Hyperactivity, Vocalisation[1] Neurological signs (e.g., muscle tremor, ataxia, convulsion)[1] Panting[1] Increased scratching[2]

[1] Transient
[2] For the first hour following administration; presumably caused by flea response to the veterinary medicinal product.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

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

Oral use.

One 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.

The veterinary medicinal product 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 orally, 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(S)

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children. Do not store above 25 °C. Do not use this veterinary medicinal product after the expiry date which is stated on the blister after Exp. The expiry date refers to the last day of that month.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product not subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 00879/5024

Cardboard box with 1, 6 and 60 tablets.
Not all pack sizes may be marketed.

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

August 2023

Detailed information on this veterinary medicinal product is available in the Union Product Database.

16. CONTACT DETAILS

Marketing authorisation holder and contact details to report suspected adverse reactions:

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

PV.GBR@elancoah.com

Manufacturer responsible for batch release: Elanco France S.A.S., 26 Rue de la Chapelle, F-68330 Huningue, France

17. 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.

UK (GB and Northern Ireland)
POM-V: To be supplied only on veterinary prescription.

Approved 29 August 2023