ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Capstar 11,4 mg tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Nitenpyram, 11.4 mg/tablet

3. PACKAGE SIZE

1 tablet
6 tablets
60 tablets

4. TARGET SPECIES

Cats and dogs.

5. INDICATIONS

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.

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 OF THE MARKETING AUTHORISATION HOLDER

Elanco logo

14. MARKETING AUTHORISATION NUMBERS

Vm 52127/3022

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

polyamide/aluminium/PVC-aluminium blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Capstar

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Nitenpyram 11.4 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Capstar 11.4 mg tablets for cats and small dogs

2. Composition

One tablet contains:
Active substance: Nitenpyram 11.4 mg

Excipient:

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

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

3. Target species

Cats and dogs.

4. Indications for use

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

5. Contraindications

None.

6. Special warnings

Special warnings:
Do not use on animals less than 4 weeks old or weighing less than 1 kg as these groups of animals were not studied.

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

Cat and dog:

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, routes and method of administration

Oral use.
One tablet should be given to cats and small dogs weighing 1 kg to 11.0 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 periods

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 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 or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product not subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 52127/3022
Cardboard box with 1, 6 and 60 tablets.
Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:
Elanco GmbH
Heinz-Lohmann Strasse 4
Groden
27472 Cuxhaven
Germany

PV.XXI@elancoah.com
Tel: +44 3308221732

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.

Gavin Hall
Approved: 30 April 2026