ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Capstar 57 mg tablets for large dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One tablet contains:
Active substance:
Nitenpyram 57 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 “HIH”, on the other side with “CG”.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

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

3.3 Contraindications

None.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Do not use on dogs weighing less than 11 kg.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
None.

Special precautions for the protection of the environment:
Not applicable.

3.6 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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Can be used during pregnancy and lactation.
Laboratory studies in rats and rabbits have produced no evidence of teratogenic or foetotoxic effects and the safety of the product was demonstrated in pregnant and lactating cats and dogs.

3.8 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.

3.9 Administration routes and dosage

Oral use.
The minimum effective recommended dose is 1 mg/kg, with the following recommendations:
One 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.
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.

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP53BX02.

4.2 Pharmacodynamics

The active ingredient, nitenpyram belongs to the chemical class of neonicotinoids which bind and inhibit insect specific nicotinic acetylcholine receptors. Nitenpyram interferes with nerve transmission and leads to the death of adult fleas. Nitenpyram does not inhibit acetylcholinesterase.

Effects on fleas (Ctenocephalides felis) may be seen as soon as 15-30 minutes after administration of the product to the host animal. This coincides with the first blood meal taken by fleas after sufficient blood levels are reached. Between 95% and 100% efficacy is observed within the first 6 hours and 100% efficacy is reached within 24 hours with no residual activity.

4.3 Pharmacokinetics

Nitenpyram is rapidly and to over 90% absorbed from the gastrointestinal tract of cats and dogs. Feeding does not affect absorption in dogs. Feeding slightly delays Tmax in cats without affecting the other pharmacokinetic properties and without affecting efficacy. The maximum blood concentration is reached after 0.5 to 2 hours in both fasted target species and the elimination half-life is about 4 hours in dogs and 8 hours in cats. More than 90% is eliminated in the urine within 1 day in dogs and 2 days in cats, mainly as the unchanged molecule.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

5.3 Special precautions for storage

Do not store above 25 °C.

5.4 Nature and composition of immediate packaging

Cardboard box with 1 polyamide/aluminium/PVC-aluminium blister. Each blister contains 1 tablet.
Cardboard box with 1 or 10 polyamide/aluminium/PVC-aluminium blisters. Each blister contains 6 tablets.
Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco

7. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 19/08/2002

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

To be completed nationally

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product not subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (*https://medicines.health.europa.eu/veterinary*).

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 57 mg tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Nitenpyram, 57 mg/tablet

3. PACKAGE SIZE

1 tablet
6 tablets
60 tablets

4. TARGET SPECIES

Dog.

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

To be completed nationally

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 57 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 57 mg tablets for large dogs

2. Composition

One tablet contains:
Active substance: Nitenpyram 57 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 “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 warnings

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, routes and method of administration

Oral use.
One 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 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 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 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

To be completed nationally
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

MM/YYYY

Detailed information on this veterinary medicinal product is available in the Union Product Database (*https://medicines.health.europa.eu/veterinary*).

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions: *To be completed nationally*

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.