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

7. MARKETING AUTHORISATION NUMBER

Vm 00879/3020

8. DATE OF FIRST AUTHORISATION

03 August 2001

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

August 2023

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*).

Approved 29 August 2023