SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Advantage 400 mg spot-on solution for dogs (≥ 25 kg)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 4.0 ml unit dose (pipette) contains:

Active substance:

Imidacloprid 400 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Benzyl alcohol (E1519)	
Propylene carbonate	
Butylhydroxytoluene (E321)	1.0 mg/ml

Clear yellow to slightly brownish solution

3. CLINICAL INFORMATION

3.1 Target species

Dogs

3.2 Indications for use for each target species

For the prevention and treatment of flea infestations and for the treatment of biting lice (*Trichodectes canis*).

Fleas on dogs are killed within one day following treatment. One treatment prevents further flea infestation for four weeks. The veterinary medicinal product can be used as part of a treatment strategy for the control of Flea Allergy Dermatitis (FAD) where this has been previously diagnosed by a veterinary surgeon.

3.3 Contraindications

Do not treat unweaned puppies of less than 8 weeks of age.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the veterinary medicinal product should be based on confirmation of the parasitic species and burden, or of the risk of infestation based on its epidemiological features, for each individual animal.

The possibility that other animals in the same household can be a source of re-infection with fleas and biting lice should be considered, and these should be treated as necessary with an appropriate product.

Re-infestation from emergence of new fleas in the environment may continue to occur for six weeks or longer after treatment is initiated. More than one treatment may therefore be required, depending on the level of fleas in the environment. To aid reduction in environmental challenge, the additional use of a suitable environmental treatment against adult fleas and their developing stages is recommended, especially of the animal's basket, bedding and regular resting areas such as carpets and soft furnishings. In order to reduce further the environmental challenge, it is recommended that all dogs in the household are treated. Treatment of nursing bitches controls flea infestations on both dam and offspring.

The veterinary medicinal product remains effective if the animal becomes wet, for example after swimming or exposure to heavy rain. However, in cases of frequent swimming or bathing re-treatment may become necessary, depending on the presence of fleas in the environment. In these cases do not treat more frequently than once weekly.

3.5 Special precautions for use

Special precautions for safe use in the target species:

This veterinary medicinal product is for topical use and should not be administered orally.
Care should be taken to avoid the contents of the pipette coming into contact with the eyes or mouth of the recipient animal.
Do not allow recently treated animals to groom each other.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

This veterinary medicinal product contains benzyl alcohol and may cause skin sensitisation or transient skin reactions in rare cases (for example, irritation, tingling).
People with known hypersensitivity to imidacloprid and benzyl alcohol should avoid contact with the veterinary medicinal product.
Avoid contact between the veterinary medicinal product and skin, eyes or mouth. Do not massage the application site.
Do not eat, drink or smoke during application.
Wash off any skin contamination with soap and water.

If the veterinary medicinal product gets into eyes accidentally, the eyes should be thoroughly flushed with water. If skin or eye irritation persists, or the veterinary medicinal product is accidentally swallowed, seek medical advice immediately and show the package leaflet or the label to the physician.
After application, do not stroke or groom animals until application site is dry.
Wash hands thoroughly after use.

Special precautions for the protection of the environment:

Imidacloprid is toxic to aquatic organisms. To avoid adverse effects on aquatic organisms, treated dogs should not be allowed to enter surface water for 48 hours after treatment. See also section 5.5.

Other precautions:

The solvent in this veterinary medicinal product may stain certain materials including leather, fabrics, plastics and finished surfaces. Allow the application site to dry before permitting contact with such materials.

3.6 Adverse events

Dogs.

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Agitation Hypersalivation[1] Disorientation, Neurological signs (e.g. Depression, Incoordination, Tremor) Application site reaction (e.g. Hair loss, Itching, Reddening of the skin, Skin lesion)

[1]May occur if the dog licks the application site immediately after treatment due to the bitter taste. This is not a sign of intoxication and disappears within some minutes without treatment.

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:

No primary embryotoxic, teratogenic or reproductive toxic effects have been observed during the studies with imidacloprid on rats and rabbits. Studies on pregnant and lactating bitches together with their offspring are limited. Evidence so far suggests that no adverse effects are to be expected in these animals.

3.8 Interaction with other medicinal products and other forms of interaction

No incompatibility has been observed between this veterinary medicinal product at twice the recommended dose and the following commonly used veterinary medicinal products: fenthion, lufenuron, milbemycin, febantel, pyrantel and praziquantel. The compatibility of the veterinary medicinal product was also demonstrated with a wide range of routine treatments under field conditions including vaccination.

3.9 Administration routes and dosage

Spot-on use. For external use only.

Underdosing could result in ineffective use and may favour resistance development. To ensure a correct dosage, body weight should be determined as accurately as possible.

Dosage and treatment schedule
The recommended minimum dose is 10 mg imidacloprid per kg body weight (bw), equivalent to 0.1 ml/kg bw of the veterinary medicinal product.

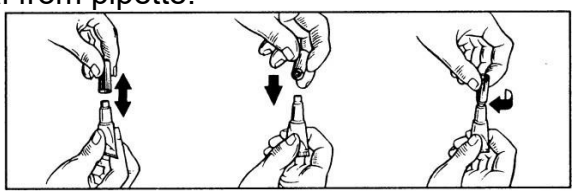
Dog weight (kg bw	Pipette size to be used	Pipette volume (ml)	Imidacloprid (mg/kg bw)
≥ 25 < 40 kg	Advantage 400 mg for dogs	4.0	minimum of 10
≥ 40 kg	Use the appropriate combination of pipettes		minimum of 10

For dogs smaller 25 kg bw, use an appropriate available pipette size to achieve the recommended dose for the weight of the animal to be treated.
For dogs of more than 40 kg bw, use an appropriate combination of available pipette sizes to achieve the recommended dose of 10 mg/kg bw.

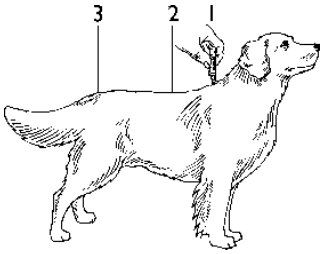
For treatment or prevention of infestations with the parasites indicated for use of this veterinary medicinal product, the need for and frequency of re-treatment(s) should be based on professional advice and should take into account the local epidemiological situation and the animal's lifestyle.

In case of biting louse infestation, a further veterinary examination 30 days after treatment is recommended as some animals may require a second treatment.

Method of administration
Remove one pipette from the package. For dogs of 40 kg body weight and greater use two pipettes. Hold pipette in an upright position, twist and pull off cap. Use reversed cap to twist and remove seal from pipette.



The dog should be standing for easy application. The entire contents of the pipette(s) should be applied evenly to three or four spots all located at different application sites along the dog's backline from the shoulder to the base of the tail. At each spot part the coat until the skin is visible.



Place the tip of the pipette on the skin and gently squeeze to expel a portion of the contents directly onto the skin.

Do not apply an excessive amount of solution at any one spot that could cause some of the solution to run off the side of the dog. Correct application will minimise the opportunity for the dog to lick the veterinary medicinal product. Apply only to undamaged skin.

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

No adverse clinical signs were produced by either individual doses of up to 200 mg/kg body weight (five to eight times the therapeutic dose), daily treatments at 100 mg/kg body weight for five consecutive days or weekly treatments at five times the maximum dose rate for eight consecutive weeks.

In rare cases of overdose or licking of treated fur, nervous system disorders (such as twitching, tremors, ataxia, mydriasis, miosis, lethargy) can occur.

Poisoning following inadvertent oral uptake in animals is unlikely. In this event, treatment should be symptomatic under veterinary medical attention. There is no known specific antidote but administration of activated charcoal may be beneficial.

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: QP53AX17

4.2 Pharmacodynamics

Imidacloprid, 1-(6-Chloro-3-pyridylmethyl)-N-nitro-imidazolidin-2-ylideneamine is an ectoparasiticide belonging to a group of chloronicotinyl compounds. Chemically, it is more accurately described as a chloronicotinyl nitroguanidine.

The substance has a high affinity for the nicotinergic acetylcholine receptors in the post-synaptic region of the central nervous system (CNS). The ensuing inhibition of cholinergic transmission in insects results in paralysis and death. Due to the weak nature of the interaction with mammalian nicotinergic receptor sites and the postulated poor penetration through the blood/brain barrier in mammals, it has virtually no effect on the mammalian CNS. The minimal pharmacological activity in mammals is supported by safety studies involving systemic administration of sub-lethal doses to rabbits, mice and rats.

In further studies, in addition to the adulticide flea efficacy of imidacloprid, a larvicidal flea efficacy in the surroundings of the treated pet has been demonstrated. Larval stages in the pet's surroundings are killed following contact with a treated animal.

4.3 Pharmacokinetics

The veterinary medicinal product is indicated for cutaneous administration. Following topical application in dogs, the solution is quickly distributed over the animal. Acute dermal studies in the rat and target animal overdose and serum kinetic studies have established that systemic absorption is very low, transient and not relevant for the clinical efficacy. This has been further demonstrated by a study in which fleas were not killed after having fed on previously treated animals once the animal's skin and fur had been cleaned of all active material.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions. Keep the blister in the outer carton.

5.4 Nature and composition of immediate packaging

White polypropylene unit dose pipette closed with white polypropylene screw cap.
Unit dose pipettes are packed in polyvinyl chloride and aluminium foil blisters.

Pack sizes
Cardboard box containing a total of 1, 2, 3, 4 or 6 unit dose pipettes in a blister sheet.
Each unit dose pipette contains 4.0 ml of solution.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater.

The veterinary medicinal product should not enter water courses as imidacloprid may be dangerous for fish and other aquatic organisms.

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

7. MARKETING AUTHORISATION NUMBER

Vm 00879/4103

8. DATE OF FIRST AUTHORISATION

25 January 1999

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

April 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product not subject to prescription.

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

Gavin Hall
Approved: 20 August 2025