

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Advantage 400 mg spot-on solution for extra large dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each unit dose (tube) contains:

Active substances:

	Unit dose	Imidacloprid
Advantage for dogs (≥ 25 kg)	4.0 ml	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)	3328 mg
Propylene carbonate	
Butylhydroxytoluene (E321)	4 mg

Clear yellow to 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*) on dogs of 25 kg body weight and greater.

Fleas on dogs are killed within one day following treatment. One treatment prevents further flea infestation for four weeks.

For dogs less than 25 kg body weight, use the appropriate Advantage spot-on product.

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

Special warnings:

If signs of disease persist or appear, consult a veterinary surgeon.

Re-infestation from emergence of new fleas in the environment may continue to occur for six weeks or longer after treatment is initiated. To aid reduction in environmental challenge, the additional use of a suitable environmental treatment against adult fleas and their developing stages is recommended. In order to reduce further the environmental challenge, it is recommended that all dogs, cats and rabbits in the household are treated, as necessary, with an appropriate product. 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 exposure to heavy rain or after swimming. However, 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.

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 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 biting lice should be considered, and these should be treated as necessary with an appropriate product.

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 tube 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 product contains benzyl alcohol and may cause skin sensitisation or transient skin reactions (for example, irritation, tingling).

Do not get the product on your skin or in your eyes or mouth.

If you get the product on your skin, wash it off with soap and water.

If you get the product in your eyes, wash your eyes thoroughly with clean water.

If the product causes any irritation to your skin or eyes that is persistent, contact your doctor.

If the product is swallowed, contact your doctor immediately. Do not eat, drink or smoke whilst using this product.

Wash hands thoroughly after use.

After application, do not stroke or groom animals until application site is dry.

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.

Other precautions:

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

3.6 Adverse events

Dogs.

<u>Very rare</u> <u>(<1 animal / 10,000 animals</u> <u>treated, including isolated</u> <u>reports):</u>	<u>Agitation</u> <u>Hypersalivation¹</u> <u>Disorientation, Nervous system disorder (e.g.</u> <u>Depression, Incoordination, Tremor)</u> <u>Skin reactions (e.g. Hair loss, Itching, Reddening of</u> <u>the skin, Skin lesion)</u>
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¹May 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 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.

Consult your veterinary surgeon before using in pregnant or nursing 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.

Do not use simultaneously with other flea products which are applied directly onto the animal.

3.9 Administration routes and dosage

Spot-on use.

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.

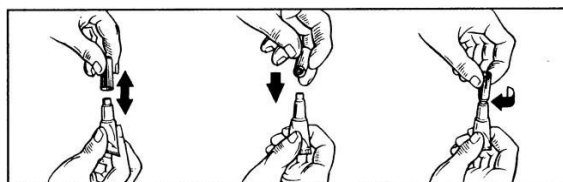
Dosage and treatment schedule

Dog (kg bw)	Product	Number of Tubes	mg/kg bw
25 to less than 40	Advantage 400 mg spot- on solution for extra large dogs	1 x 4.0 ml	maximum of 16
40 and greater	Advantage 400 mg spot- on solution for extra large dogs	2 x 4.0 ml	maximum of 20
For dogs less than 25 kg body weight: use the appropriate Advantage spot-on for dogs			

Fleas are killed within one day following treatment. One treatment prevents further flea infestation on dogs for up to 4 weeks. Should re-treatment become necessary earlier than 4 weeks, do not re-treat more frequently than weekly.

Method of administration

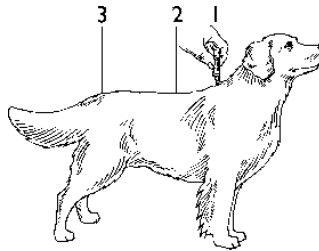
Remove one tube from the package. Hold tube in an upright position, twist and pull off cap. Use reversed cap to twist and remove seal from tube. After use, replace cap on tube.



For dogs of 25 to less than 40 kg body weight only:

The dog should be standing for easy application. The entire contents of the tube should be applied evenly to three or four spots on the top of the back 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 tube on the skin and gently squeeze to expel a portion of the contents directly onto the skin.



For Dogs of 40 kg body weight and greater only:

Remove two tubes from the package. Using the techniques described above apply the entire contents of each tube 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.

For all dogs:

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 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 (eight times the normal dose), daily treatments of 100 mg/kg 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 (CAS-No. 138261-41-3)* 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 nicotinic 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 nicotinic 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.

5.4 Nature and composition of immediate packaging

White polypropylene unit dose tube closed with white polypropylene screw cap. Unit dose tubes in multiple packs are packed in polyvinyl chloride and aluminium foil blisters. Unit dose tube in a single pack is packed without a blister.

Pack sizes

Cardboard box containing a total of 1 unit dose tube or 2, 3, 4 or 6 unit dose tubes in a blister sheet. Each unit dose tube 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 GmbH

7. MARKETING AUTHORISATION NUMBERS

Vm 52127/5159

Vm 52127/3084

8. DATE OF FIRST AUTHORISATION

03 April 2007

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

November 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: 27 February 2026