SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Advantage 40 mg Spot-on Solution for Small Cats, Small Dogs and Pet Rabbits

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each unit dose (pipette) contains:

Active substances:

	Unit dose	**Imidacloprid**
Advantage 40 mg (< 4 kg)	0.4 ml	40 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)	332.8 mg
Butylhydroxytoluene (E321)	0.4 mg
Propylene carbonate	

Clear yellow to slightly brownish solution

3. CLINICAL INFORMATION

3.1 Target species

Cats, dogs and pet rabbits

3.2 Indications for use for each target species

Prevention and treatment of flea infestations and treatment of biting lice *(Trichodectes canis)* on dogs of less than 4 kg. For dogs of 4 kg body weight and greater use the appropriate Advantage product –see section 3.9.

Prevention and treatment of flea infestations on cats of less than 4 kg body weight. For cats of 4 kg body weight and greater use the appropriate Advantage product – see section 3.9.

Treatment of flea infestations on pet rabbits of less than 4 kg body weight. For rabbits of 4 kg body weight and greater use the appropriate Advantage product – see section 3.9.

Fleas are killed within one day following treatment. One treatment prevents further flea infestation for four weeks on dogs, three to four weeks on cats and one week on pet rabbits

3.3 Contraindications

Do not treat unweaned puppies or kittens of less than 8 weeks of age.
Do not use on pet rabbits of less than 10 weeks of age.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

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 and queens 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 (dogs). 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 (dogs) should be considered, and these should be treated as necessary with an appropriate product.

3.5 Special precautions for use

<u>Special precautions for safe use in the target species:</u>

This veterinary medicinal product is for topical use and should not be administered orally.
Apply only to undamaged skin.
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.
Any collar should be removed prior to application of the veterinary medicinal product. Prior to re-fitting the collar, the treated area should be visually assessed to ensure it is dry.

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

Keep stored tubes in the original packaging until ready to use. In order to prevent children from getting access to used tubes, dispose of used tubes immediately.
People with known hypersensitivity to imidacloprid should avoid contact with the veterinary medicinal product.
This product contains benzyl alcohol and may cause sensitisation or transient skin reactions (e.g. irritation, tingling).
Avoid contact between the veterinary medicinal product and skin, eyes or mouth.
Do not massage the application site.
If the veterinary medicinal product gets into eyes, flush thoroughly 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.
Do not eat, drink or smoke during application.
Wash hands thoroughly after use.
Wash off any skin contamination with soap and water.
After application, do not stroke or groom treated animals until the application site is dry (typically within an hour or so). It is therefore recommended that animals are not treated during the day, but should be treated during the early evening, and that recently treated animals are not allowed to sleep with owners, especially children.

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 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 Diarrhoea, Hypersalivation[1], Vomiting Disorientation, Neurological disorders (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.

Cats and rabbits.

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Agitation Diarrhoea[1], Hypersalivation[2], Vomiting[3] Neurological disorders (e.g. Depression, Incoordination, Tremor) Application site reaction (e.g. Hair loss, Itching, Reddening of the skin, Skin lesion)

[1]May occur after oral ingestion.
[2]May occur if the cat 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.
[3] May occur after oral ingestion, in cats.

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

No reproductive toxic effects have been observed in rats and no primary embryotoxic or teratogenic toxic effects have been observed during the studies on rats and rabbits. Studies on pregnant and lactating bitches, queens and does 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: lufenuron, febantel, pyrantel and praziquantel (dogs) and lufenuron, pyrantel and praziquantel (cats). 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.
This product is for external use only and should not be administered orally.
Underdosing could result in ineffective use and may favour resistance development.
To ensure correct dosage, body weight should be determined as accurately as possible.

Dosage and treatment schedule

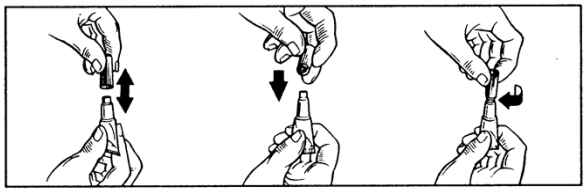
Cat/Dog	Product	Number of Tubes	mg/kg bw
Less than 4 kg body weight	Advantage 40 mg Spot- On Solution for Small Cats, Small Dogs and Pet Rabbits	1 x 0.4 ml	Minimum of 10
Cats of 4 kg body weight and greater should receive 1 tube Advantage 80 mg Spot-On Solution for Large Cats & Pet Rabbits Dogs of 4 kg body weight and greater should receive the appropriate Advantage for Dogs product.			

Rabbit	Product	Number of Tubes	mg/kg bw
Adult (greater than 10 weeks) less than 4 kg body weight	Advantage 40 mg Spot- On Solution for Small Cats, Small Dogs and Pet Rabbits	1 x 0.4 ml	Minimum of 10
Rabbits of 4 kg body weight and greater should receive 1 tube Advantage 80 mg Spot-On Solution for Large Cats & Pet Rabbits			

In case of biting lice infection (*Trichodectes canis*) in dogs, a veterinary examination 30 days after treatment is recommended as some animals may require a second treatment.

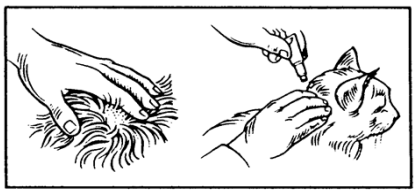
Method of administration

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.

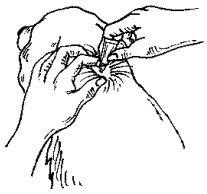


<u>Administration to the cat</u>

Part the hair on the cat's neck at the base of the skull until the skin is visible. Place the tip of the tube on the skin and squeeze firmly several times to empty the contents directly onto the skin.



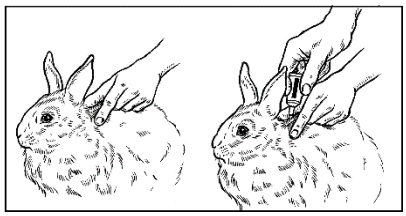
Administration to the dog



With the dog in the standing position, part the coat between the shoulder blades until the skin is visible. Place the tip of the tube on the skin and squeeze firmly several times to empty the contents directly onto the skin.

Administration to the Rabbit

Part the hair on the rabbit's neck at the base of the skull until the skin is visible. Place the tip of the tube on the skin and squeeze firmly several times to empty the contents directly onto the skin.



All Species

Correct application will minimise the opportunity for the animal to lick off the product. Apply only to undamaged skin. Do not allow recently treated animals to groom each other.

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

In cats, no adverse clinical signs were produced using doses of five times the therapeutic level weekly for eight consecutive weeks.

In dogs, no adverse clinical signs were produced by 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 rabbits, no adverse clinical signs were seen using doses of up to 45 mg/kg body weight (4 times the therapeutic level) weekly for 4 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, in cats.

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

Do not use on rabbits intended for human consumption.

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, 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 Size	Cardboard box containing 1 unit dose tube (without a blister) or 2, 3, 4 or 6 unit dose tubes in a blister sheet. Each unit dose pipette contains 0.4 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. Do not contaminate ponds, waterways or ditches with the product or empty containers.

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 52127/5161
Vm 52127/3086

8. DATE OF FIRST AUTHORISATION

14 August 2001

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: 21 November 2025