1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Advantage 80 mg spot-on solution for cats and pet rabbits (≥4 kg)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.8 ml unit dose (pipette)contains:

Active substance:
Imidacloprid 80 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)	832.0 mg/ml
Butylhydroxytoluene (E321)	1.0 mg/ml
Propylene carbonate	

Clear yellow to slightly brownish solution.

3. CLINICAL INFORMATION

3.1 Target species

Cats and pet rabbits.

3.2 Indications for use for each target species

For cats:
Prevention and treatment of flea *(Ctenocephalides felis)* infestations.

For pet rabbits:
Treatment of flea infestations.

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

The veterinary medicinal product can be used as part of a treatment strategy for the control of Flea Allergy Dermatitis (FAD) in cats, where this has been previously diagnosed by a veterinary surgeon.

3.3 Contraindications

Do not treat unweaned 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

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 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 cats and rabbits in the household are treated. Treatment of nursing 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. 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.

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.
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:

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, see 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

Cats:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Agitation Diarrhoea[1], Hypersalivation[2], Vomiting[1] Neurological signs (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.

Rabbits:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Agitation Diarrhoea[1], Hypersalivation[2] 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 rabbit 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 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 queens 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, 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. 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.

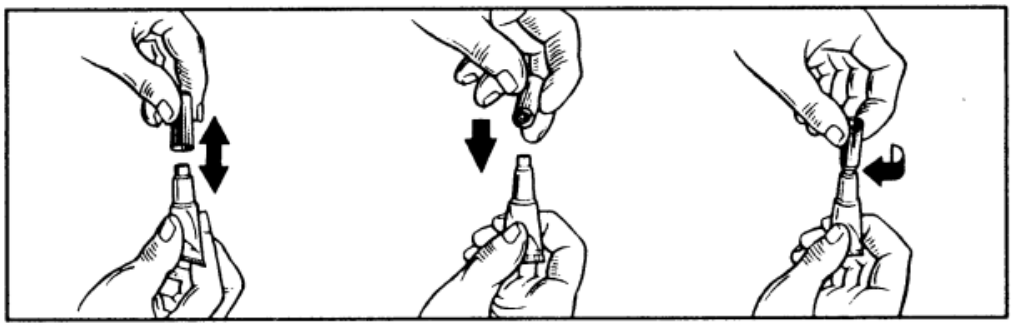
Cat/Pet rabbit weight (kg)	Pipette size to be used	Pipette volume (ml)	Imidacloprid (mg/kg bw)
≥4 kg	Advantage 80 mg for cats and pet rabbits	0.8	minimum of 10

For cats or pet rabbits smaller 4 kg bw, use the appropriate available pipette size for the weight of the animal to be treated.

For treatment or prevention of infestations with fleas, 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.

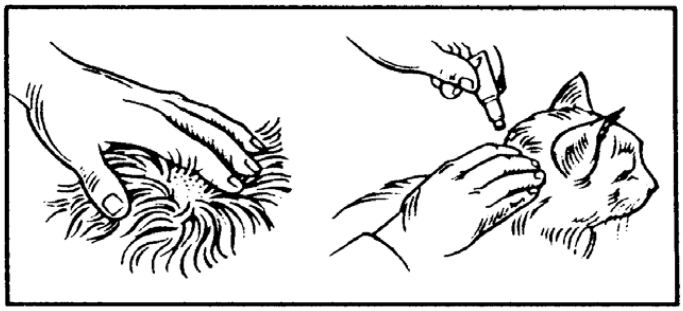
Method of administration:

Remove one pipette from the package. Hold pipette in an upright position, twist and pull off cap. Use reversed cap to twist and remove seal from pipette.



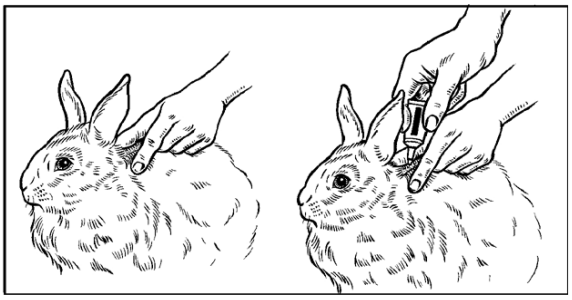
Administration to the cat

Part the hair on the cat's neck at the base of the skull until the skin is visible. Place the tip of the pipette on the skin and squeeze firmly several times to empty the contents directly onto the skin. Application at the base of the skull will minimize the opportunity for the cat to lick the veterinary medicinal product. Apply only to undamaged 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. Application at the base of the skull will minimize the opportunity for the rabbit to lick the veterinary medicinal product. Apply only to undamaged skin.



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 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 in cats, 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 2, 3, 4 or 6 unit dose pipettes in a blister sheet.
Each unit dose pipette contains 0.8 ml of solution.

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.

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 NUMBER(S)

VPA22020/052/002

8. DATE OF FIRST AUTHORISATION

24/02/2012

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

23/04/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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