PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Cardboard Box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Advantage 250 mg spot-on solution

2. STATEMENT OF ACTIVE SUBSTANCES

Each 2.5 ml tube contains:

250 mg imidacloprid

3. PACKAGE SIZE

1 pipette
2 pipette
3 pipette
4 pipette
6 pipette

4. TARGET SPECIES

≥ 10 < 25 kg

5. INDICATIONS

Flea prevention and flea and biting louse (*Trichodectes canis*) treatment for dogs weighing 10 kg to less than 25 kg.

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

Flea

Louse

6. ROUTES OF ADMINISTRATION

Spot-on use

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

IMPORTANT: Use correctly to safeguard the health of you and your pet. Read the enclosed Product Information Leaflet carefully before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco logo

14. MARKETING AUTHORISATION NUMBERS

Vm 52127/5158
Vm 52127/3083

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {Tube label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Advantage

≥ 10 < 25 kg

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

2.5 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {Blister*}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Advantage

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

250 mg imidacloprid

2.5 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

**NB: There is no blister foil for the single tube presentation*

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Advantage 100 mg spot-on solution for medium dogs
Advantage 250 mg spot-on solution large dogs
Advantage 400 mg spot-on solution for extra-large dogs

2. Composition

Each unit dose (tube) contains:

	Unit Dose	Imidacloprid
Advantage 100 for medium dogs (≥ 4 < 10 kg)	1.0 ml	100 mg
Advantage 250 for large dogs (≥ 10 < 25 kg)	2.5 ml	250 mg
Advantage 400 for extra-large dogs (≥ 25 kg)	4.0 ml	400 mg

Excipients:

1 mg/ml Butylhydroxytoluene (E321)

Clear yellow to slightly brownish solution

3. Target species

Dogs.

4. Indications for use

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.

5. Contraindications

Do not treat unweaned puppies of less than 8 weeks of age.

Do not use in case of hypersensitivity to the active substance or to any of the excipients.

6. 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 package leaflet 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.

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 the application site to dry before permitting contact with such materials.

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.

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.

Overdose:

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.

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.

7. Adverse events

Dogs.

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Agitation (hyperactivity) Hypersalivation[1] (drooling) Disorientation (confusion), Nervous system disorder (e.g. Depression (lethargy), Incoordination, Tremor) Application site reactions (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 product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

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
4 to less than 10	Advantage 100 mg spot-on solution for medium dogs	1 x 1.0 ml	10 - 25
10 to less than 25 kg	Advantage 250 mg spot-on solution for large dogs	1 x 2.5 ml	10 - 25
25 to less than 40 kg	Advantage 400 mg spot- on solution for extra large dogs	1 x 4.0 ml	maximum of 16
40 kg and greater	Advantage 400 mg spot- on solution for extra large Dogs	2 x 4.0 ml	maximum of 20

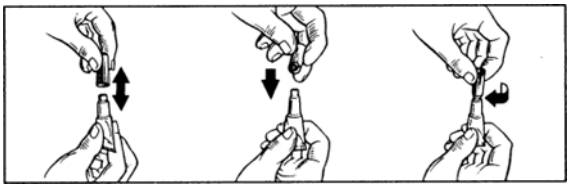
Dogs weighing less than 4 kg: use Advantage Spot-on Solution for Small Cats, Small Dogs and Pet Rabbits.

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.

9. Advice on correct 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 less than 25 kg body weight:

With the dog in the standing position, part the coat between the shoulder blades until the skin is visible.

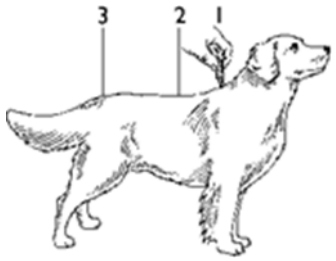
Place the tip of the tube on the skin and squeeze firmly several times to empty the contents directly onto the skin.

For dogs of 25 kg body weight and greater:

The dog should be standing for easy application. The entire contents of the tube(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 as shown.

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.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions. Do not use this veterinary medicinal product after the expiry date which is stated on the carton and tube after Exp. The expiry date refers to the last day of that month.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

This 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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product not subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Product Name	Vm Number
Advantage 100 mg spot-on solution for medium dogs	52127/5157 & 52127/3082
Advantage 250 mg spot-on solution for large dogs	52127/5158 & 52127/3083
Advantage 400 mg spot-on solution for extra-large dogs	52127/5159 & 52127/3084

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 tube contains 1.0 ml, 2.5 or 4.0 ml of solution.

Not all pack sizes may be marketed.

15. PID link (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

Elanco GmbH
Heinz-Lohmann Strasse 4
Groden
27472 Cuxhaven
Germany

+44 3308221732
PV.GBR@elancoah.com
PV.XXI@elancoah.com

Manufacturer responsible for batch release:

KVP Pharma + Veterinär Produkte GmbH
Projensdorfer Str. 324, 24106 Kiel
Germany

17. Other information

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.

AVM-GSL

Gavin Hall
Approved: 27 February 2026