PACKAGE LEAFLET
Advantage Spot-on solution for Dogs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder
Elanco Europe Ltd, Form 2, Bartley Way, Bartley Wood Business Park, Hook RG27 9XA, United Kingdom

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Advantage 40 Spot-on solution for Dogs
Advantage 100 Spot-on solution for Dogs
Advantage 250 Spot-on solution for Dogs
Advantage 400 Spot-on solution for Dogs
Imidacloprid

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Active substance:
10 % (100 mg/ml) Imidacloprid

Excipient(s):
0.1 % (1 mg/ml) Butylhydroxytoluene (E 321), Benzyl alcohol

Each pipette contains:

	Pipette	Imidacloprid	E321
Advantage 40 for Dogs (< 4 kg)	0.4 ml	40 mg	0.4 mg
Advantage 100 for Dogs (≥ 4 < 10 kg)	1.0 ml	100 mg	1.0 mg
Advantage 250 for Dogs (≥ 10 < 25 kg)	2.5 ml	250 mg	2.5 mg
Advantage 400 for Dogs (≥ 25 kg)	4.0 ml	400 mg	4.0 mg

4. INDICATION(S)

For the prevention and treatment of flea infestations and for the treatment of biting lice (*Trichodectes canis*) on dogs.
Fleas on dogs are killed within one day following treatment. One treatment prevents further flea infestation for four weeks. The 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.

5. CONTRAINDICATIONS

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

Do not use in animals that are known to be hypersensitive to the active substance or any of the excipients

6. ADVERSE REACTIONS

The product is bitter tasting and salivation may occasionally occur if the dog licks the application site immediately after treatment. This is not a sign of intoxication and disappears within some minutes without treatment.
In very rare occasions skin reactions such as hair loss, redness, itching and skin lesions may occur. Agitation and disorientation has also been reported. Excessive salivation and nervous signs such as incoordination, tremors and depression have been reported exceptionally in dogs.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Any instructions given by a veterinary surgeon for the use of this product should be followed.

Dosage and Treatment Schedule

Dog (kg bw)	Product	Number of Pipettes	Imidacloprid (mg/kg bw)
Less than 4 kg	Advantage 40 for Dogs	1 x 0.4 ml	minimum of 10
4 to less than 10 kg	Advantage 100 for Dogs	1 x 1.0 ml	minimum of 10
10 to less than 25 kg	Advantage 250 for Dogs	1 x 2.5 ml	minimum of 10
25 to less than 40 kg	Advantage 400 for Dogs	1 x 4.0 ml	minimum of 10
40 kg and greater	Advantage 400 for Dogs	2 x 4.0 ml	minimum of 10

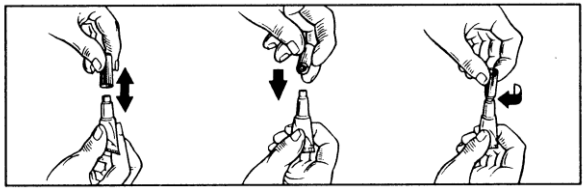
Re-infestation from emergence of new fleas in the environment may continue to occur for six weeks or longer after treatment is initiated. More than one treatment may therefore be required, depending on the level of fleas in the environment. To aid in environmental challenge, the additional use of a suitable environmental treatment against adult fleas and their developing stages is recommended.

The 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 re-treat more frequently than once weekly.

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 (Advantage 400 for Dogs). Hold pipette in an upright position, twist and pull off cap. Use reversed cap to twist and remove seal from pipette.



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 pipette on the skin and squeeze firmly several times to empty the contents directly onto the skin. (See figure 1)

For dogs of 25 kg body weight and greater:
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. (See figure 2)

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

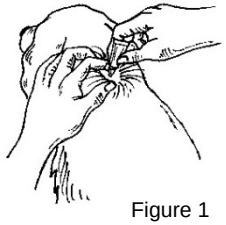


Figure 1

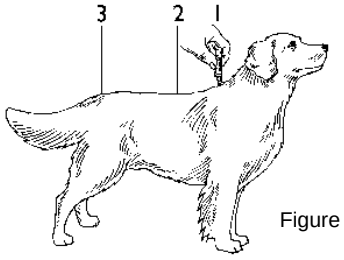


Figure 2

9. ADVICE ON CORRECT ADMINISTRATION

For external use only.
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 minimize the opportunity for the dog to lick the product, please also refer to section *Adverse Reactions*.
Apply only to undamaged skin. Do not allow recently treated animals to groom each other.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Store away from food, drink and animal feeding stuffs.
Keep the blister in the outer carton.

12. SPECIAL WARNING(S)

Special precautions for use in animals

This product is for topical use and should not be administered orally.
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.
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.

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.

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

Wash hands thoroughly after use.
Wash off any skin contamination with soap and water.
People with known skin sensitivity may be particularly sensitive to this product.
Avoid contact of the product with the eyes or mouth.
If the product gets into eyes accidentally, the eyes should be thoroughly flushed with water. If skin or eye irritation persists, or the product is accidentally swallowed, obtain medical attention.
Do not eat, drink or smoke during application.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

Any unused product or waste materials should be disposed of in accordance with national requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED: October 2020

15. OTHER INFORMATION

Pack sizes 0.4 / 1.0 / 2.5 / 4.0 ml solution per pipette
Pack containing 1, 2, 3, 4, or 6 unit dose pipettes
Not all pack sizes may be marketed.

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.

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

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