# PACKAGE LEAFLET FOR: ADVANTAGE 40 mg SPOT-ON SOLUTION FOR SMALL CATS, SMALL DOGS AND PET RABBITS

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

MA holder: Elanco Europe Ltd. Form 2, Bartley Way Bartley Wood Business Park Hook RG27 9XA United Kingdom

Manufactured by: KVP Pharma + Veterinär Produkte GmbH, Projensdorfer Str. 324, D-24106 Kiel, Germany.

#### 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Advantage 40 mg Spot-On Solution for Small Cats, Small Dogs & Pet Rabbits less than 4 kg

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

Each 0.4 ml tube contains 40 mg imidacloprid.

#### 4. INDICATION(S)

For the prevention and treatment of fleas on small cats and small dogs. Treatment of fleas on pet rabbits and for the treatment of biting lice (*Trichodectes canis*) on small dogs.

#### 5. CONTRAINDICATIONS

Do not use this product on cats, rabbits and dogs weighing 4 kg or over.

Do not treat unweaned kittens or puppies of less than 8 weeks of age or rabbits aged less than 10 weeks.

#### 6. ADVERSE REACTIONS

The product is bitter tasting and salivation may occasionally occur if the animal licks the application site immediately after treatment. This is not a sign of intoxication and disappears within a few minutes without treatment. Correct application will minimise the opportunity for the animal to lick the product.

In very rare occasions skin reactions such as hair loss, redness, itching and skin lesions may occur. Agitation has also been

reported. Excessive salivation and nervous signs such as incoordination, tremors and depression have been reported exceptionally in cats.

Oral ingestion may result in other gastrointestinal signs (vomiting and diarrhoea), which have been observed very rarely, in cats, based on post-marketing data.

#### 7. TARGET SPECIES

Cats, dogs and pet rabbits.

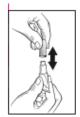
## 8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

#### Dosage and administration

One tube should be applied to cats, dogs and pet rabbits weighing less than 4 kg (equivalent to a minimum dose of 10 mg/kg imidacloprid). This dose will provide protection against flea infestation for 4 weeks on the dog, 3 - 4 weeks on the cat and up to 1 week on the rabbit. The product can be used as part of a treatment strategy for the control of Flea Allergy Dermatitis (FAD) in cats and dogs where this has been previously diagnosed by a veterinary surgeon.

#### 9. ADVICE ON CORRECT ADMINISTRATION

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







#### Administration to the Cat

Part the hair on the cat's neck at the base of the skull until the skin is visible.

Revised: December 2021 AN: 00946/2021





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. Rabbits of more than 4 kg body weight should receive 1 tube Advantage 80 mg Spot-On Solution for Large Cats & Pet Rabbits.

#### **All Species**

Do not rub in. Apply only to undamaged skin. For optimal prevention and control of flea infestation, monthly treatments are recommended in the cat and dog. For rabbits, retreat at the interval recommended by your veterinary surgeon.

The 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.

#### 10. WITHDRAWAL PERIOD(S)

Do not use in rabbits intended for human consumption.

#### 11. SPECIAL STORAGE PRECAUTIONS

Store away from food, drink and animal feedingstuffs. Keep container in outer carton.

Do not use this veterinary medicinal product after the expiry date which is stated on the label.

The expiry date refers to the last day of that month

#### 12. SPECIAL WARNING(S)

#### FOR EXTERNAL USE ONLY

#### FOR ANIMAL TREATMENT ONLY

Do not allow recently treated animals to groom each other. 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 use in cases of hypersensitivity to the active substance or to any of the excipients

Any collar should be removed prior to application of the product. Prior to re-fitting the collar, the treated area should be visually assessed to ensure it is dry.

#### **Operator Safety**

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 (for example, irritation, tingling).

Avoid contact of the product with the skin, eyes and 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 product gets into eyes accidentally, the eyes should be thoroughly flushed with water. If skin or eye irritation persists, obtain medical attention.

If the product is accidentally swallowed, obtain medical attention immediately.

Wash hands thoroughly after use After application, do not stroke or groom animals until the application site is dry.

#### **General Precautions**

Keep out of the sight and reach of children.

Re-infestation from emergence of new fleas in the environment may continue for 6 weeks or longer after treatment. 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 cats, dogs and rabbits in the household are treated.

The 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.

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

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.

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

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.

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

Dispose of used packaging in the household refuse. Unused product should be returned to the veterinary surgeon.

The product should not enter water courses as this may be dangerous for fish and other aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty containers.

# 14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED November 2021

Revised: December 2021 AN: 00946/2021

#### 15. OTHER INFORMATION

Packaging style: Blister packs containing either 2, 3, 4 or 6 unit dose tubes or a single unit dose tube without blister.

Pack size: Carton contains 1 tube or 1, 5, 10 or 20 blisters each with 2, 3, 4 or 6 tubes. Not all pack sizes may be marketed.

In recent studies, in addition to the adulticide flea efficacy of imidacloprid, a larvicidal flea efficacy in the surroundings of the treated cat or dog has been demonstrated. Larval stages in the cat's or dog's surroundings are killed following contact with a treated animal.

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 and queens 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: lufenuron, febantel, pyrantel and praziquantel (dogs) and lufenuron, pyrantel and praziquantel (cats). The compatibility of the product was also demonstrated with a wide range of routine treatments under field conditions including vaccination.

**NFA-VPS** 

Vm 00879/4100