

PARTICULARS TO APPEAR ON THE OUTER PACKAGE: CARTON

SINGLE TUBE CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Advantage 40 mg Spot-On Solution for Small Cats, Small Dogs & Pet Rabbits

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active substance: Imidacloprid 100 mg/ml

Each 0.4 ml pipette contains:

Active substance:

40 mg imidacloprid;

0.4 mg butylhydroxytoluene

3. PHARMACEUTICAL FORM

Spot-on solution.

Spot-on solution for topical application.

4. PACKAGE SIZE

1 pipette (1 x 0.4 ml)

5. TARGET SPECIES

Cats, dogs and pet rabbits.

6. INDICATION(S)

Flea prevention and treatment for cats and dogs less than 4 kg, treatment of fleas on pet rabbits and treatment of biting lice (*Trichodectes canis*) on dogs.

For the prevention and treatment of flea infestations and for the 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.

For the prevention and treatment of flea infestations on cats of less than 4 kg bodyweight. For cats of 4 kg body weight and greater use the appropriate Advantage product.

For the treatment of flea infestations on pet rabbits. For rabbits of 4 kg body weight and greater use the appropriate Advantage product. Fleas are killed within one day following treatment. One treatment prevents further flea infestation for up to four weeks on dogs, three to four weeks on cats and up to one week on pet rabbits.

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.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For external use only.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

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.

For animal treatment only.

10. EXPIRY DATE

Expiry:

11. SPECIAL STORAGE CONDITIONS

Keep container in outer carton.

Store away from food, drink and animal feeding stuffs.

Do not use after expiry date.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet before use.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

For animal treatment only

NFA-VPS

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER

Vm 00879/4100

17. MANUFACTURER'S BATCH NUMBER

Batch No.:

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

PARTICULARS TO APPEAR ON THE OUTER PACKAGE: CARTON

MULTI-TUBE CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active substance: Imidacloprid 100 mg/ml

3. PHARMACEUTICAL FORM

Spot-on solution for topical application.

4. PACKAGE SIZE

2, 3, 4, 6 x 0.4 ml

This pack comprises 2, 3, 4, 6 tubes, each containing 40 mg imidacloprid per 0.4 ml tube.

5. TARGET SPECIES

Cats, dogs and pet rabbits.

6. INDICATION(S)

Flea prevention and treatment for cats and dogs less than 4 kg, treatment of fleas on pet rabbits and treatment of biting lice (*Trichodectes canis*) on dogs.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

IMPORTANT: USE CORRECTLY TO SAFEGUARD YOUR PET AND YOUR HEALTH. READ THE INSTRUCTION LEAFLET BEFORE USE.

Dosage

One tube should be applied to cats and dogs weighing less than 4 kg (equivalent to a minimum dose of 10 mg/kg imidacloprid) and to pet rabbits. 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.

8. WITHDRAWAL PERIOD

Do not use in rabbits intended for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

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

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

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 animals that are known to be hypersensitive to the active substance or any of the excipients.

FOR EXTERNAL USE ONLY.

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

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

10. EXPIRY DATE

Expiry:

11. SPECIAL STORAGE CONDITIONS

Keep container in outer carton.

Store away from food, drink and animal feeding stuffs.

Do not use after expiry date.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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

The product should not enter water courses as this may be dangerous for fish and other aquatic organisms.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

FOR ANIMAL TREATMENT ONLY

NFA-VPS

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER

Vm 00879/4100

17. MANUFACTURER'S BATCH NUMBER

Batch No.:

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

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS:**

TUBE LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Contains 40 mg imidacloprid per 0.4 ml tube.

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

0.4 ml

4. ROUTE(S) OF ADMINISTRATION

5. WITHDRAWAL PERIOD

Do not use in rabbits intended for human consumption.

6. BATCH NUMBER

BN:

7. EXPIRY DATE

Exp:

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

For external use only.

Keep container in outer carton.

Vm 00879/4100

NFA-VPS

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER FOIL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

Contains 40 mg imidacloprid per 0.4 ml tube.

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd., Hook, UK.

Vm 00879/4100

3. EXPIRY DATE

For batch number and expiry date see tube.

4. BATCH NUMBER

For batch number and expiry date see tube.

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only

For external use only.

Do not use in rabbits intended for human consumption

Refer to package leaflet for full instructions and warnings.

Keep container in outer carton.

NFA-VPS

2, 3, 4, 6 x 0.4 ml tubes*

[Tube pictogram]

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

**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.

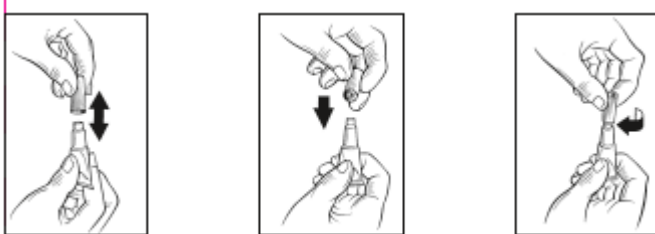
8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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.



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

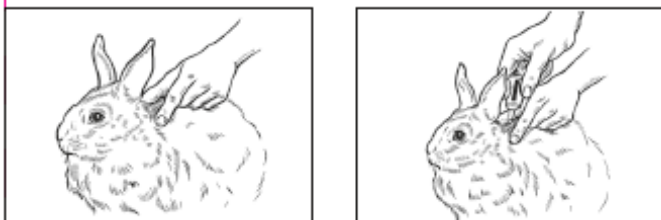
With the dog in the standing position, part the coat between the shoulder blades until the skin is visible.



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

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

Approved: 07/12/21

A handwritten signature in blue ink, appearing to read "D. Austin", with a horizontal line extending from the end of the signature.