

PARTICULARS TO APPEAR ON THE OUTER PACKAGE: CARTON

SINGLE-TUBE CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Advantage 80 mg Spot-On Solution for Large Cats and Pet Rabbits

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active substance: Imidacloprid 100 mg/ml

Each 0.8 ml pipette contains:

Active substance:

80 mg imidacloprid;

0.8 mg butylhydroxytoluene

3. PHARMACEUTICAL FORM

Spot-on solution.

Spot-on solution for topical application.

4. PACKAGE SIZE

1 pipette (1 x 0.8 ml)

5. TARGET SPECIES

Cats and pet rabbits

6. INDICATION(S)

Flea prevention and treatment for cats and treatment of fleas on pet rabbits weighing more than 4 kg.

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

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

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 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.

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.

10. EXPIRY DATE

Expiry:

11. SPECIAL STORAGE CONDITIONS

Store away from food, drink or animal feedingstuffs.

Do not use after expiry date.

After use replace cap on tube.

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.

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| NFA-VPS |
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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 00879/4105

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 80 mg spot-on solution For Large Cats and Pet Rabbits

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 0.8 ml

This pack comprises 2, 3, 4, 6 tubes each containing 0.8 ml of a 10% w/v cutaneous solution of imidacloprid (equivalent to 80 mg imidacloprid/tube).

5. TARGET SPECIES

Cats and pet rabbits

6. INDICATION(S)

Flea prevention and treatment for cats and treatment of fleas on pet rabbits weighing more than 4 kg.

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 to pet rabbits weighing 4 kg and over (equivalent to a maximum dose of 20 mg/kg imidacloprid). This dose will provide protection against flea infestation for 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 where this has been previously diagnosed by a veterinary surgeon. 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 surroundings are killed following contact with a treated animal.

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 pet rabbits weighing less than 4 kg.

Do not treat unweaned kittens 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 treated animals until the application site is dry (typically within an hour or so).

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. 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.

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.

10. EXPIRY DATE

Expiry:

11. SPECIAL STORAGE CONDITIONS

Store away from food, drink or animal feedingstuffs. Do not use after expiry date. After use replace cap on tube.

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 the 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.

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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 00879/4105

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: PIPETTE LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Advantage 80 mg spot-on solution
For large cats & pet rabbits 4 kg and over

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Contains 10% w/v imidacloprid.

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

0.8 ml

4. ROUTE(S) OF ADMINISTRATION

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

BN:

7. EXPIRY DATE

Exp:

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

For external use only.

For operator warnings see carton.

Vm 00879/4105

NFA-VPS

[Elanco logo]

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER FOIL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Advantage 80 mg spot-on solution
For Large Cats & Pet Rabbits 4 kg and over

Contains 10% w/v imidacloprid.

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd., Hook, UK
Vm 00879/4105

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.

Keep in outer carton.

Read package leaflet before use.

For operator warnings see carton.

2, 3, 4, 6 x 0.8 ml tubes*

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[Elanco logo] [Tube pictogram]

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

**PACKAGE LEAFLET FOR: ADVANTAGE 80 mg SPOT-ON SOLUTION FOR
LARGE CATS & 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 80 mg spot-on solution For Large Cats & Pet Rabbits

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

Each tube contains 0.8 ml of a 10% w/v cutaneous solution of imidacloprid
(equivalent to 80 mg imidacloprid/tube).

4. INDICATION(S)

For the prevention and treatment of fleas on cats of 4 kg and over and treatment of
fleas on pet rabbits 4 kg and over.

5. CONTRAINDICATIONS

Do not use this product on cats or pet rabbits weighing less than 4 kg.
Do not treat unweaned kittens of less than 8 weeks of age or rabbits of less than 10
weeks of age.

6. ADVERSE REACTIONS

The product is bitter tasting and salivation may occasionally occur if the cat licks the
application site immediately after treatment. This is not a sign of intoxication and
disappears within a few minutes without treatment. Correct application at the base
of the skull will minimise the opportunity for the pet 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 and pet rabbits.

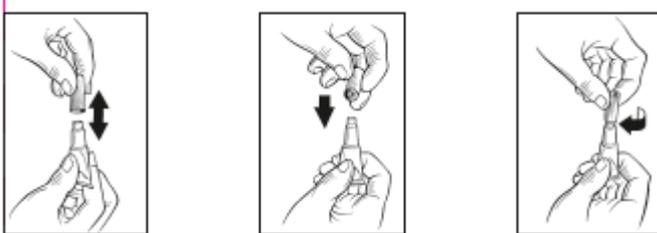
8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Dosage and administration

One tube should be applied to cats and pet rabbits weighing 4 kg and over (equivalent to a maximum dose of 20 mg/kg imidacloprid). This dose will provide protection against flea infestation in the cat for 3 - 4 weeks 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 where this has been previously diagnosed by a veterinary surgeon.

9. ADVICE ON CORRECT ADMINISTRATION

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



Part the hair on the pet'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 its contents directly onto the skin. Do not rub in. Apply only to undamaged skin. For optimal prevention and control of flea infestation, monthly treatments are recommended.

The efficacy of the product may be reduced if the animal becomes markedly wet. If retreatment becomes necessary earlier than 4 weeks, treatment may be repeated. Do not apply more frequently than weekly.

10. WITHDRAWAL PERIOD(S)

Do not use on rabbits intended for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Store away from food, drink or animal feedingstuffs.

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. After use replace cap on tube.

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 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 (e.g. 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 treated animals until the application site is dry (typically within an hour or so).

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.

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.

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 pet has been demonstrated. Larval stages in the pet'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 queens together with their offspring are limited. Evidence so far suggests that no adverse effects are to be expected in these animals.

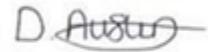
No incompatibility has been observed between this product at twice the recommended dose and the following commonly used veterinary products: lufenuron, pyrantel and praziquantel (cats). The compatibility of the product was also

demonstrated with a wide range of routine treatments under field conditions including vaccination.

NFA-VPS

Vm 00879/4105

Approved: 07/12/21

A handwritten signature in blue ink that reads "D. Austin". The signature is written in a cursive style with a horizontal line extending from the end.