

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**  
**Outer carton, pack size of 2, 3, 4 and 6 pipettes.**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Advantage® 40 mg feline and bunny Spot-on solution  
Imidacloprid

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Each 0.4 ml pipette contains:  
Active substance: 40 mg imidacloprid;  
0.4 mg butylhydroxytoluene (E 321)  
332.8 mg benzyl alcohol (E 1519)

**3. PHARMACEUTICAL FORM**

Spot-on solution

**4. PACKAGE SIZE**

2 pipettes (2x 0.4 ml)  
3 pipettes (3x 0.4 ml)  
4 pipettes (4x 0.4 ml)  
6 pipettes (6x 0.4 ml)

**5. TARGET SPECIES**

Cats and pet rabbits

**6. INDICATION(S)**

Flea (*Ctenocephalides felis*) prevention and treatment for cats less than 4 kg.  
Flea treatment for pet rabbits less than 4 kg.  
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.



[Pictogram – flea]

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

For external use only.  
Read the package leaflet before use.

**8. WITHDRAWAL PERIOD**

Do not use on rabbits intended for human consumption.

**9. SPECIAL WARNING(S), IF NECESSARY**

Read the package leaflet before use.

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

Do not use on pet rabbits of less than 10 weeks of age.

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

**10. EXPIRY DATE**

EXP {month/year}

**11. SPECIAL STORAGE CONDITIONS**

Keep the blister in the outer carton.

**12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS; IF ANY**

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements. Imidacloprid may adversely affect aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty containers.

**13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable**

For animal treatment only.

*[Prescription status to be completed nationally; Blue Box]*

**14. THE WORDS “KEEP OUT OF THE REACH AND SIGHT 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

Manufactured by  
KVP Pharma + Veterinär Produkte GmbH

Projensdorfer Str. 324, 24106 Kiel  
Germany

**16. MARKETING AUTHORISATION NUMBER**

Vm 00879/4099

**17. MANUFACTURER'S BATCH NUMBER**

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING  
UNITS**  
Pipette label

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Advantage®

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

Imidacloprid(e) 40mg

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

0.4 ml

**4. ROUTE(S) OF ADMINISTRATION**

**5. WITHDRAWAL PERIOD**

**6. BATCH NUMBER**

Lot {number}

**7. EXPIRY DATE**

EXP {month/year}

**8. THE WORDS "FOR ANIMAL TREATMENT ONLY"**

[Cat-Pictogram]



< 4kg

[Rabbit-Pictogram]



< 4kg

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**

{Blister}

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Advantage® 40mg feline and bunny Spot-on solution  
Imidacloprid

**2. NAME OF THE MARKETING AUTHORISATION HOLDER**

Elanco logo

**3. EXPIRY DATE**

EXP {month/year}

**4. BATCH NUMBER**

Lot {number}

**5. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only

[Cat-Pictogram]



< 4kg

[Rabbit-Pictogram]



< 4kg

0.4 ml

## PACKAGE LEAFLET

Advantage® Spot-on solution for Cats and Pet Rabbits

### 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 responsible for batch release

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

### 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Advantage® 40 mg feline and bunny Spot-on solution [UK]

Advantage® 80 mg feline and bunny Spot-on solution [UK]

Imidacloprid

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

Each pipette of clear yellow to slightly brownish solution contains:

	0.4 ml	0.8 ml
<b>Active substance</b>		
Imidacloprid	40 mg	80 mg
<b>Excipients:</b>		
Butylhydroxytoluene (E321)	0.4 mg	0.8 mg
Benzyl alcohol (E1519)	332.8 mg	665.6 mg

#### **4. INDICATION(S)**

For the prevention and treatment of flea (*Ctenocephalides felis*) infestations on cats and for the treatment of flea infestations on pet rabbits.

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.

#### **5. CONTRAINDICATIONS**

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

Do not use on pet rabbits of less than 10 weeks of age.

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

#### **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 some minutes without treatment.

In very rare occasions (less than 1 animal in 10,000 animals, including isolated reports) skin reactions such as hair loss, redness, itching and skin lesions may occur in cats and rabbits. Agitation, excessive salivation and nervous signs such as incoordination, tremors and depression have also been reported but exceptionally in cats.

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

#### **7. TARGET SPECIES**

Cats and pet rabbits

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

This product is for topical use and should not be administered orally. Animals should be weighed accurately prior to treatment.

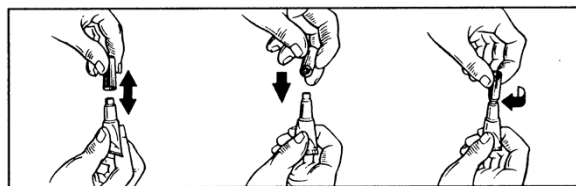
Any instructions given by a veterinary surgeon for the use of this product should be followed.

### *Dosage and Treatment Schedule*

Cat/Rabbit (kg bw)	Product	Number of Pipettes	Imidacloprid (mg/kg bw)
< 4 kg	Advantage® 40 for Small Cats and Small Pet Rabbits	1 x 0.4 ml	minimum of 10
≥ 4 kg	Advantage® 80 for Large Cats and Large Pet Rabbits	1 x 0.8 ml	minimum of 10

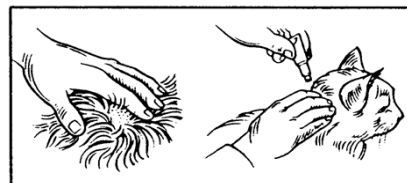
### *Method of Administration*

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



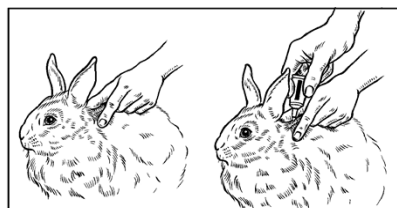
### Administration to the Cat

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



## **9. ADVICE ON CORRECT ADMINISTRATION**

For external use only.



Application at the base of the skull will minimize the opportunity for the cat 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**

Do not use on rabbits intended for human consumption.

## **11. SPECIAL STORAGE PRECAUTIONS**

Keep out of the sight and reach of children.

Keep the blister in the outer carton.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton, blister and pipette after EXP. The expiry date refers to the last day of that month.

## **12. SPECIAL WARNING(S)**

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. In order to reduce further the environmental challenge, it is recommended that all cats and rabbits in the household are treated. Treatment of nursing queens and does controls flea infestations on both dam and offspring.

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 re-treat more frequently than once weekly.

### **Special precautions for use in animals**

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

Apply only to undamaged skin

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.

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

Do not massage the application site.

This product contains benzyl alcohol and may cause skin sensitisation or transient skin reactions in rare cases (for example, irritation, tingling).

Avoid contact between the product and skin, eyes or mouth.

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 application site is dry.  
People with known hypersensitivity to imidacloprid should avoid contact with the veterinary medicinal product.

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

*[to be adapted nationally, if required]*

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements. Imidacloprid may adversely affect 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**

October 2020

### **15. 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.

The solvent in this 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.

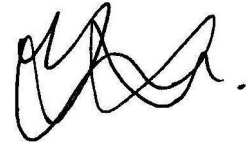
No reproductive toxic effects have been observed in rats and no primary embryotoxic or teratogenic toxic effects have been observed during the studies on rats and rabbits. Studies on pregnant and lactating queens together with their offspring are limited. Evidence so far suggests that no adverse effects 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. The compatibility of the product was also demonstrated with a wide range of routine treatments under field conditions including vaccination.

Pack sizes      0.4 ml / 0.8 ml solution per pipette; blister pack containing 2, 3, 4, or 6 unit dose pipettes  
Container      White polypropylene pipettes with caps

Not all pack sizes may be marketed.

*[Further information like prescription status or marketing authorisation numbers to be completed nationally, if required]*

A handwritten signature in black ink, consisting of several loops and a final horizontal stroke.

Approved: 23 October 2020