

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Outer carton, pack size of 1, 2, 3, 4 and 6 pipettes

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Advantage® 40 for Cats

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 0.4 ml pipette contains:
Active substance: 40 mg imidacloprid;
0.4 mg butylhydroxytoluene.

3. PHARMACEUTICAL FORM

Spot-on solution

4. PACKAGE SIZE

1 pipette (1x 0.4 ml)
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

6. INDICATION(S)

Flea prevention and treatment for cats less than 4 kg.
One treatment prevents further flea infestation for three to 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.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

8. WITHDRAWAL PERIOD

Read the package leaflet before use.
Do not treat unweaned kittens of less than 8 weeks of age.
Keep the blister in the outer carton.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

Expiry/EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

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

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 reach and sight 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 00879/4101

17. MANUFACTURER’S BATCH NUMBER

Batch/Lot {number}



[Pictogram – flea]

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

Pipette label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Advantage 40 Spot-on Solution for Cats

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

10% imidacloprid(e)

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

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

[Cat-Pictogram]



< 4kg

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

{Blister}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Advantage 40 Spot-on Solution for Cats

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd.

3. EXPIRY DATE

4. BATCH NUMBER

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

[Cat-Pictogram]



< 4kg

0.4 ml

PACKAGE LEAFLET

Advantage® Spot-on solution for Cats

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 Cats
Advantage® 80 Spot-on solution for Cats
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 cats (< 4 kg)	0.4 ml	40 mg	0.4 mg
Advantage 80 for cats (≥ 4 kg)	0.8 ml	80 mg	0.8 mg

4. INDICATION(S)

For the prevention and treatment of flea infestations on cats.

One treatment prevents further flea infestation for three to 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 kittens 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 cat 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 has also been reported. Excessive salivation and nervous signs such as incoordination, tremors and depression have been reported 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

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

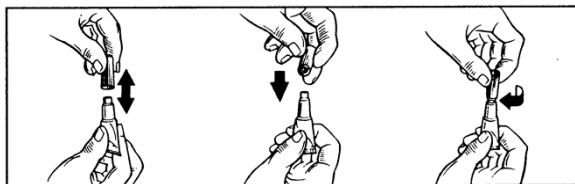
Cat (kg bw)	Product	Number of Pipettes	Imidacloprid (mg/kg bw)
Less than 4 kg	Advantage® 40 for Cats	1 x 0.4 ml	minimum of 10
4 kg and greater	Advantage® 80 for Cats	1 x 0.8 ml	minimum of 10

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.

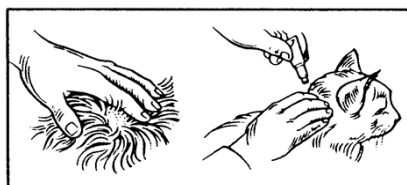
The product remains effective if the animal becomes wet, for example after exposure to heavy rain. However, re-treatment may become necessary, depending on the presence of fleas in the environment. In these cases do not re-treat more frequently than once weekly.

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.



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.



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

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.

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

[to be adapted nationally, if required]

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 / 0.8 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 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.
[Further information like prescription status or marketing authorisation numbers to be completed nationally, if required]

A handwritten signature in black ink, consisting of several vertical strokes followed by a horizontal line and a small flourish.

Approved 14 October 2020