PARTICULARS TO APPEAR ON THE OUTER PACKAGE – Cardboard Box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Advantix 400 mg + 2000 mg spot-on solution

2. STATEMENT OF ACTIVE SUBSTANCES

Each 4.0 ml pipette contains:
400 mg imidacloprid, 2000 mg permethrin

3. PACKAGE SIZE

1 pipette

2 pipettes

3 pipettes

4 pipettes

6 pipettes

24 pipettes

4. TARGET SPECIES

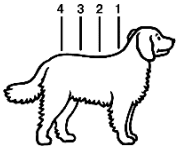
> 25 kg ≤ 40 kg

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Spot-on use.
For external use only.
One pipette for dogs > 25 kg ≤ 40 kg

[Dog Application –Pictogram (size specific corresponding to the product size]



Do not use on puppies of less than 7 weeks of age or 25 kg of weight.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Use within 2 years after opening the foil pouch.
Once the pipette is broached use immediately

9. SPECIAL STORAGE PRECAUTIONS

Do not freeze.
After opening the foil pouch store in a dry place at a temperature not above 30°C.
Keep the foil pouch with the blisters in the outer carton.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco GmbH

14. MARKETING AUTHORISATION NUMBERS

Vm 52127/5126
Vm 52127/3051

15. BATCH NUMBER

Lot {number}

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Advantix

> 25 kg ≤ 40 kg

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

4.0 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS – Blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Advantix

> 25 kg ≤ 40 kg

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

4.0 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS - Foil pouch

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Advantix

> 25 kg ≤ 40 kg

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

4.0 ml

100 mg/ml imidacloprid
500 mg/ml permethrin

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Use within 2 years after opening the foil pouch.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Advantix 40 mg + 200 mg spot-on solution for dogs (≤4 kg)
Advantix 100 mg + 500 mg spot-on solution for dogs (>4 kg ≤ 10 kg)
Advantix 250 mg + 1250 mg spot-on solution for dogs (> 10 kg ≤ 25 kg)
Advantix 400 mg + 2000 mg spot-on solution for dogs (> 25 kg ≤ 40 kg)
Advantix 600 mg + 3000 mg spot-on solution for dogs (> 40 kg ≤ 60 kg)

2. Composition

Each pipette contains:

	Pipette	**Imidacloprid**	**Permethrin**	**N-Methylpyrrolidone**	**Butylhydroxytoluene (E321)**
Advantix 40 mg + 200 mg for dogs (≤ 4 kg)	0.4 ml	40 mg	200 mg	194 mg	0.4 mg
Advantix 100 mg + 500 mg for dogs (> 4 kg ≤ 10 kg)	1.0 ml	100 mg	500 mg	484 mg	1.0 mg
Advantix 250 mg + 1250 mg for dogs (> 10 kg ≤ 25 kg)	2.5 ml	250 mg	1250 mg	1210 mg	2.5 mg
Advantix 400 mg + 2000mg for dogs (> 25 kg ≤ 40 kg)	4.0 ml	400 mg	2000 mg	1936 mg	4.0 mg
Advantix 600 mg + 3000 mg for dogs (> 40 kg ≤ 60 kg)	6.0 ml	600 mg	3000 mg	2904 mg	6.0 mg

For dogs > 60 kg the appropriate combination with other sized pipettes should be used.
Clear yellowish to brownish solution.

3. Target species

Dogs.

4. Indications for use

For dogs with, or at risk from mixed infestations by fleas, biting lice, ticks, sand flies, mosquitos and stable flies. The veterinary medicinal product is only indicated when use against parasites targeted by each of the combined active substances is indicated at the same time.

For the treatment and prevention of flea (*Ctenocephalides canis, Ctenocephalides felis*) infestation.

Fleas on dogs are killed within one day following treatment. One treatment prevents further flea infestation for four weeks. The veterinary medicinal product can be used as part of a treatment strategy for flea allergy dermatitis (FAD).

Treatment of biting lice (*Trichodectes canis)*.
The veterinary medicinal product has persistent acaricidal and repellent efficacy against tick infestations (*Rhipicephalus sanguineus* and *Ixodes ricinus* for four weeks, and *Dermacentor reticulatus* for three weeks).

Reduction of the risk of transmission of the vector-borne pathogen *Ehrlichia canis*, thereby reducing the risk of canine ehrlichiosis by acaricidal and repellent activity on the tick vector *Rhipicephalus sanguineus.* The reduction in risk has been shown to begin from three days following application of the veterinary medicinal product and to persist for four weeks.

Ticks already on the dog may not be killed within two days after treatment and may remain attached and visible. Therefore the removal of ticks already on the dog at the time of treatment is recommended, in order to prevent them from attaching and having a blood meal.

One treatment provides repellent (anti-feeding) activity against sand flies (*Phlebotomus papatasi* for two weeks and *Phlebotomus perniciosus* for three weeks), against mosquitoes (*Aedes. aegypti* for two weeks and *Culex. pipiens* for four weeks) and against stable flies (*Stomoxys. calcitrans*) for four weeks.

Reduction of the risk of transmission infection of the vector-borne pathogen *Leishmania infantum,* thereby reducing the risk of canine leishmaniosis by repellent (anti-feeding) activity on sandflies (vector *Phlebotomus papatasi* for two weeks and

vector *Phlebotomus perniciosus* for three weeks). The effect is indirect due to veterinary medicinal product's activity against the vector.

Sand flies	*P. perniciosus*	3 weeks
	P. papatasi	2 weeks
Mosquitoes	*A. aegypti*	2 weeks
	C. pipiens	4 weeks
Stable flies	*S. calcitrans*	4 weeks

5. Contraindications

In the absence of available data the veterinary medicinal product should not be used on puppies of less than 7 weeks of age or 1.5 kg of weight. According to the dog's body weight the corresponding veterinary medicinal product must be used, see dosing scheme.
Do not use in cases of hypersensitivity to the active substances or to any of the excipients.
Do not use on cats.

6. Special warnings

Special warnings:

It is recommended to apply the treatment at least three days before expected exposure to *Ehrlichia canis*. With regard to *E. canis*, studies have demonstrated a reduced risk of canine ehrlichiosis in dogs exposed to *Rhipicephalus sanguineus* ticks infected with *E. canis* from three days following application of the veterinary medicinal product and to persist for four weeks.

Immediate protection against sandflies bites is not documented. Treated dogs for the reduction of the risk of infection with *Leishmania infantum* via transmission by sandflies *Phlebotomus perniciosus* should be kept in a protected environment during the first 24 hours after the initial treatment application.

To reduce re-infestation from emergence of new fleas, it is recommended to treat all dogs in a household. Other animals living in the same household should also be treated with a suitable product. To aid further in reducing environmental challenge, the additional use of a suitable environmental treatment against adult fleas and their developmental stages is recommended.

The veterinary medicinal product remains effective if the animal becomes wet. However, prolonged, intense exposure to water should be avoided. In cases of frequent water exposure the persistent efficacy may be reduced. In these cases do not retreat more frequently than once weekly. If a dog requires a shampoo, it should be administered before applying the veterinary medicinal product or at least 2 weeks after application, to optimise efficacy of the veterinary medicinal product.

The possibility that other animals in the same household can be a source of re-infection with fleas, biting lice, ticks, mosquitoes and flies should be considered, and these should be treated as necessary with an appropriate product.

In the absence of risk of co-infection, a narrow spectrum veterinary product should be used. The use of this veterinary medicinal product should take into account local information about susceptibility of the target parasites, where available.

Unnecessary use of antiparasitics or use deviating from the instructions given in the leaflet may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the product should be based on confirmation of the parasitic species and burden, or of the risk of infestation based on its epidemiological features, for each individual animal.

In Europe, resistance to pyrethroids has been reported in isolated cases of *Rhipicephalus sanguineus* and *Stomoxys calcitrans*. Current knowledge suggests that resistance in both parasites is conferred by gene mutations at the target site while other factors like metabolic detoxification may also play a role.

Special precautions for safe use in the target species:

Care should be taken to avoid the content of the pipette coming into contact with the eyes or mouth of the recipient dogs.

Care should be taken to administer the veterinary medicinal product correctly as described under *Method of Administration*. In particular oral uptake due to the licking of the application site by treated or in-contact animals should be avoided.

Do not use on cats.

This veterinary medicinal product is extremely poisonous to cats and could be fatal due to the unique physiology of cats which is unable to metabolise certain compounds including permethrin. To prevent cats from being accidentally exposed to the veterinary medicinal product, keep treated dogs away from cats after treatment until the application site is dry. It is important to ensure that cats do not groom the site of application on a dog, which has been treated with this veterinary medicinal product. Seek veterinary advice immediately if this occurs.

Consult your veterinary surgeon before using the veterinary medicinal product on sick and debilitated dogs.
Ticks will be killed and fall off the host within 24 to 48 hours after infestation without having a blood meal, as a rule. An attachment of single ticks after treatment cannot be excluded. For this reason, a transmission of infectious diseases cannot be completely excluded if conditions are unfavourable. The protection may be insufficient during the first hours/days after the administration of the veterinary medicinal product. However, the product provides repellent (anti-feeding) activity against ticks, sand flies and mosquitoes, thus preventing the repelled parasites from taking a blood meal and thus reducing the risk of Canine Vector-Borne Disease

(CVBD) transmission (diseases such as borreliosis, rickettsiosis, ehrlichiosis, leishmaniosis).

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

Avoid contact between the veterinary medicinal product and skin, eyes or mouth.
Do not eat, drink or smoke during application.
Wash hands thoroughly after use.
In case of accidental spillage onto skin, wash off immediately with soap and water.
People with known skin sensitivity may be particularly sensitive to this product.
People with known hypersensitivity to imidacloprid and permethrin should administer the veterinary medicinal product with caution.

The predominant clinical symptoms that in extremely rare case may be shown are transient sensory irritations of the skin like tingling, burning sensation or numbness.
If the veterinary medicinal product gets accidentally into the eyes, the eyes should be thoroughly flushed with water.
If skin or if eye irritation persists, seek medical advice immediately and show the package leaflet or the label to the physician.
Do not ingest. In case of accidental ingestion seek medical advice immediately and show the package leaflet or the label to the physician.
Treated dogs should not be handled especially by children until the application site is dry. This may be ensured by treating the dogs e.g. in the evening. Recently treated dogs should not be allowed to sleep together with their owner, especially children.

In order to prevent children from getting access to pipettes, keep the pipette in the original packaging until ready for use and dispose of used pipettes immediately.

The warning below only applies to veterinary medicinal products for dogs of more than 10 kg:
Laboratory studies in rabbits and rats with the excipient N-methylpyrrolidone have shown evidence of foetotoxic effects. The veterinary medicinal product should not be administered by pregnant women and women suspected of being pregnant. Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product by women of childbearing age.

Special precautions for the protection of the environment:

As the veterinary medicinal product is dangerous to aquatic organisms, treated dogs must not under any circumstances be allowed into any type of surface water for at least 48 hours after treatment.

Permethrin containing veterinary medicinal products are toxic to honey bees.

Other precautions:

The solvent in this veterinary medicinal product may stain certain materials including leather, fabrics, plastics and finished surfaces. Allow the application site to dry before permitting contact with such materials.

Pregnancy and lactation:

The veterinary medicinal product can be used during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:

None known.

Overdose:

No adverse clinical signs were noted in healthy puppies or adult dogs exposed to 5x overdosage or for puppies whose mothers were treated with 3x overdosage of the veterinary medicinal product.

Major incompatibilities:

None known.

7. Adverse events

Dogs.

Uncommon (1 to 10 animals / 1,000 animals treated):
Application site hair change (e.g. greasy fur), Application site itching Vomiting
Rare (1 to 10 animals / 10,000 animals treated):
Application site erythema, Application site hair loss, Application site inflammation Diarrhoea
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Agitation[1,2,4], Restlessness[1,2,4], Rolling[1,2,4] Whining[1,2,4] Hypersalivation[1,2,4] Decreased appetite[1,2,4], Lethargy[1,3] Neurological signs (Abnormal movement and Twitching)[1,2,4], Tremor[3] Rubbing[1,4], Scratching[1,4]

[1] Generally self-resolving
[2] In dogs susceptible to permethrin.
[3] Following inadvertent oral uptake in dog. There is no known specific antidote; symptomatic treatment recommended.
[4] Transient.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at https://www.gov.uk/report-veterinary-medicine-problem.

8. Dosage for each species, routes and method of administration

Spot-on use.

The recommended minimum dose is:
10 mg/kg body weight (bw) imidacloprid and 50 mg/kg body weight (bw) permethrin.

Dosing Scheme

Dogs (kg bw)	Trade name	Volume (ml)	Imidacloprid (mg/kg bw)	Permethrin (mg/kg bw)
≤ 4 kg	Advantix 40 mg + 200 mg	0.4 ml	minimum of 10	minimum of 50
> 4 kg ≤ 10 kg	Advantix 100 mg + 500 mg	1.0 ml	10 - 25	50 - 125
> 10 kg ≤ 25 kg	Advantix 250 mg + 1250 mg	2.5 ml	10 - 25	50 - 125
> 25 kg ≤ 40 kg	Advantix 400 mg + 2000 mg	4.0 ml	10 - 16	50 - 80
> 40 kg ≤ 60 kg	Advantix 600 mg + 3000 mg	6.0 ml	10 - 15	50 - 75

For dogs > 60 kg the appropriate combination with other sized pipettes should be used.

Underdosing could result in ineffective use and may favour resistance development.
To ensure a correct dosage, body weight should be determined as accurately as possible.

Ticks, fleas:
The need and frequency of re-treatment(s) should be based on local epidemiological situation and the animal's lifestyle.

Biting lice:
In case of biting louse infestation, a further veterinary examination 30 days after treatment is recommended as some animals may require a second treatment.

Sand flies:
To protect a dog over the whole sand fly season, treatment should be compliantly continued throughout.

9. Advice on correct administration

For external use only.
Apply only to undamaged skin.
Do not apply an excessive amount of solution at any one spot that could cause some of the solution to run off the side of the dog.

Method of Administration

Remove one pipette from the package. Hold applicator pipette in an upright position, twist and pull cap off. Turn the cap around and place the other end of cap back on pipette. Twist cap to break seal, then remove cap from pipette as shown in figure 1.

For dogs up to 10 kg body weight:
With the dog standing still, part the coat between the shoulder blades 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 as shown in figure 2.

<u>For dogs over 10 kg body weight:</u>

With the dog standing still, the entire contents of the pipette should be applied evenly to four spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the pipette on the skin and gently squeeze to expel a portion of the solution on the skin as shown in figure 3.

Figures are shown below.

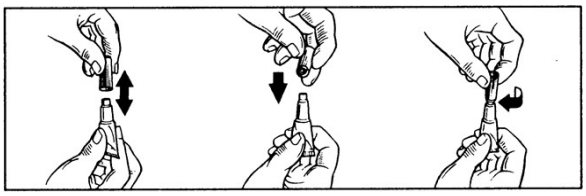


Figure 1

Figure 2

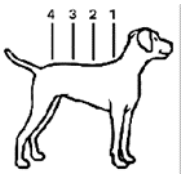


Figure 3

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not freeze.
After opening the foil pouch store in a dry place at a temperature not above 30°C.

Do not use this veterinary medicinal product after the expiry date which is stated on the pipette, foil pouch or carton after Exp. The expiry date refers to the last day of that month.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

This veterinary medicinal product should not enter water courses as imidacloprid and permethrin may be dangerous for fish and other aquatic organisms.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Advantix 40 mg + 200 mg spot-on solution for dogs (≤ 4kg) –
Vm 52127/5125; Vm 52127/3050
Advantix 100 mg + 500 mg spot-on solution for dogs (> 4 kg ≤ 10 kg) –
Vm 52127/5123; Vm 52127/3048
Advantix 250 mg + 1250 mg spot-on solution for dogs (> 10kg ≤ 25kg) –
Vm 52127/5124; Vm 52127/3049
Advantix 400 mg + 2000 mg spot-on solution for dogs (> 25 kg ≤ 40 kg) –
Vm 52127/5126; Vm 52127/3051
Advantix 600 mg + 3000 mg spot-on solution for dogs (> 40 kg ≤ 60 kg) –

Vm 00879/4110

Cardboard box containing a total of 1, 2, 3, 4, 6, or 24 unit dose pipettes in blister sheet and foil pouch. Each unit dose pipette contains 0.4 ml, 1.0 ml, 2.5 ml, 4.0 ml or 6.0 ml of solution.
Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

Elanco GmbH
Heinz-Lohmann
Strasse 4
Groden
27472
Cuxhaven Germany
PV.GBR@elancoah.com
PV.XXI@elancoah.com
Tel: +44 3308221732

Manufacturer responsible for batch release:

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

17. Other information

POM-V

This veterinary medicinal product is an ectoparasiticide for topical use containing imidacloprid and permethrin. This combination acts as an insecticide, acaricide and as a repellent.

Imidacloprid is effective against adult fleas and larval flea stages. 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 dog`s immediate surroundings are killed following contact with a treated animal.

Gavin Hall

Approved: 28 August 2026