

Product index:

Advantage

Withdrawal notes:

Do not use on rabbits intended for human consumption.

Incorporating:

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

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

Advantage 100 Spot-On Solution for Dogs

Advantage 250 Spot-On Solution for Dogs

Advantage 400 Spot-On Solution for Dogs

Presentation:

A clear yellow to slightly brownish solution containing as active substance imidacloprid. Each tube contains 0.4 ml (40 mg imidacloprid), 0.8 ml (80 mg imidacloprid), 1 ml (100 mg imidacloprid), 2.5 ml (250 mg imidacloprid) and 4.0 ml (400 mg imidacloprid) respectively as listed above. The product also contains benzyl alcohol and butylhydroxytoluene (E321) as an antioxidant.

Uses:

For the prevention and treatment of flea infestations on cats and dogs, and for the treatment of biting lice (*Trichodectes canis*) on dogs.

For the treatment of flea infestations on pet rabbits.

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 Flea Allergy Dermatitis (FAD) in the cat and the dog, where this has been previously diagnosed by a veterinary surgeon.

Dosage and administration:

Please refer to Table 1.

Dosage and Treatment Schedule:

Treatment should be repeated after four weeks. Treatment of nursing bitches and queens controls flea infestations on both dam and offspring.

Fleas are killed within one day following treatment. One treatment prevents further flea infestation on dogs and cats for up to four weeks and on rabbits for up to one week.

Should re-treatment be necessary earlier than four weeks, do not treat more frequently than weekly.

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 reduction in environmental challenge, the additional use of a suitable environmental treatment against adult fleas and 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 the case of biting louse infestation in dogs, a veterinary examination 30 days after treatment is recommended as some animals may require a second treatment.

Method of Administration

Remove one tube from the package. Hold the tube in an upright position, twist and pull off cap. Use reversed cap to twist and remove seal from tube. See Figure 1. h-532.

Figure 1. Opening a tube

Administration to the Cat/Rabbit

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 the contents directly onto the skin.

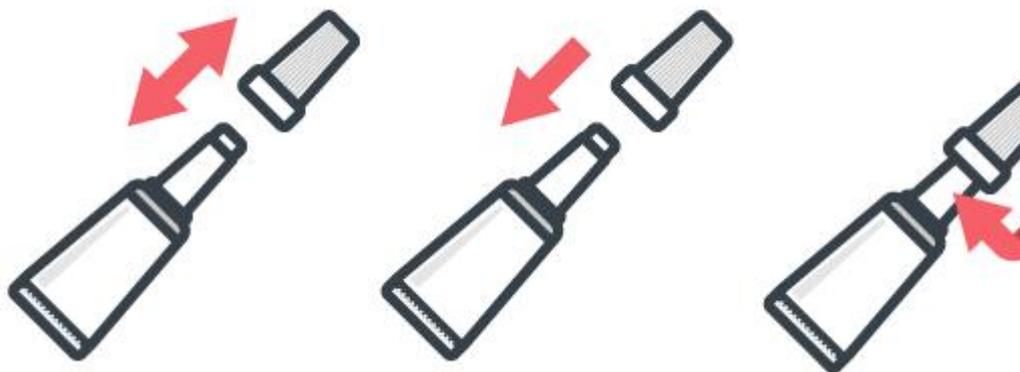


Figure 2. Correct application will minimise the opportunity for the animal to lick off the product. Apply only to undamaged skin. Do not allow recently treated animals to groom each other.

Administration to the cat/rabbit

For dogs of less than 25kg bodyweight

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.



Figure 3:

Administration to dogs up to 25kg

For dogs of 25 kg body weight and greater

The dog should be standing for easy application. The entire contents of the tube should be applied evenly to 3 or 4 spots all located at different application sites along the dog's backline from the shoulder to the base of the tail. At each spot, part the coat until the skin is visible. Place the tip of the tube on the skin and gently squeeze the tube to expel a portion of its contents directly onto the skin. Do not apply an excessive amount of solution at any one spot, as that could cause some of the product to run down the animal's side.

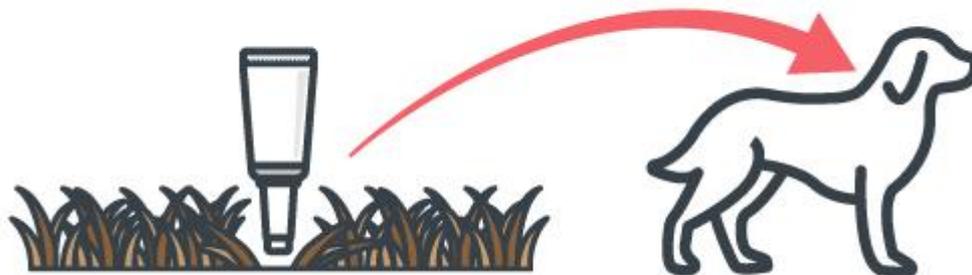


Figure 4: Administration to dogs over 25kg



For all dogs

Do not apply an excessive amount of solution at any one spot that could cause some of the solution to run down the side of the dog. The product is bitter tasting and salivation may occasionally occur if the dog licks the application site immediately after treatment. This is not a sign of intoxication and disappears within some minutes without treatment. Correct application will minimise the opportunity for the dog to lick the product. Apply only to undamaged skin. Do not allow recently treated animals to groom each other.

Use During Pregnancy and Lactation:

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, queens and does together with their offspring are limited. Evidence so far indicates that no adverse effects are to be expected in these animals.

Contra-indications, warnings, etc:

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.

Do not use in animals that are known to be hypersensitive to the active substance or any of the excipients.

Apply only to undamaged skin.

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

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 allow recently treated animals to groom each other.

For external use only.

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 (see dosage and administration).

On very rare occasions skin reactions such as hair loss, redness, itching and skin lesions may occur. Agitation and disorientation has also been reported.

Excessive salivation and nervous signs such as incoordination, tremors and depression have been reported exceptionally in dogs and cats.

No incompatibility has been observed between this product at twice the recommended dose and the following commonly used veterinary products: fenthion, lufenuron, milbemycin, 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.

In cats, no adverse clinical signs were produced using doses of five times the therapeutic level for eight consecutive weeks.

In dogs, no adverse clinical signs were produced by individual doses of up to 200 mg/kg body weight (five to eight times the therapeutic dose), daily treatments at 100 mg/kg body weight for five consecutive days or weekly treatments at five times the maximum dose rate for eight consecutive weeks.

In rabbits, no adverse clinical signs were seen using doses of up to 45 mg/kg body weight (4 times the therapeutic level) weekly for 4 consecutive weeks.

Dogs: In rare cases of overdose or licking of treated fur, nervous system disorders (such as twitching, tremors, ataxia, mydriasis, miosis, lethargy) can occur.

Poisoning following inadvertent oral uptake in either man or 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 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.

Withdrawal period(s):

Do not use on rabbits intended for human consumption.

User Safety:

Wash hands thoroughly after use.

Wash off any skin contamination with soap and water.

After application do not stroke or groom animals until the application site is dry (typically within an hour or so). People with known skin sensitivity may be particularly sensitive to the product.

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

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

If the product gets into eyes accidentally, the eyes should be thoroughly flushed with water.

If skin or eye irritation persists, seek medical attention. If the product is accidentally swallowed, obtain medical attention immediately.

Do not eat, drink or smoke during application.

Store away from food, drink or animal feeding stuffs.

Environmental Safety:

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local / national requirements.

Pharmaceutical precautions:

No special precautions for storage. Store away from food, drink and animal feeding stuffs.

Shelf-life of the veterinary medicinal product as packaged for sale: 5 years

Legal category:

Legal category: NFA-VPS

Packaging quantities:

Blister pack, containing 4 white polypropylene pipettes with caps, filled as follows:

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

4 x 0.4 ml pipettes

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

4 x 0.8 ml pipettes

Advantage 100 Spot-On Solution for Dogs

4 x 1.0 ml pipettes

Advantage 250 Spot-On Solution for Dogs

4 x 2.5 ml pipettes

Advantage 400 Spot-On Solution for Dogs

4 x 4.0 ml pipettes

Further information:

Pharmacotherapeutic group: antiparasitic products, insecticides and repellents ATCvet code: QP53AX17 Imidacloprid, 1-(6-Chloro-3-pyridylmethyl)-N-nitro-imidazolidin-2-ylideneamine is an ectoparasiticide belonging to a new group of chloronicotinyl compounds. Chemically, it is more accurately described as a chloronicotinyl nitroguanidine

Imidacloprid is an ectoparasiticide belonging to a group of chloronicotinyl compounds.

Chemically, it is more accurately described as a chloronicotinyl nitroguanidine.

The pharmacological properties of imidacloprid are novel. The substance has a high affinity for the nicotinic acetylcholine receptors in the post-synaptic region of the central nervous system (CNS). The ensuing inhibition of cholinergic transmission in insects results in paralysis and death. Due to the weak nature of the interaction with mammalian nicotinic receptor sites and the postulated poor penetration through the blood/brain barrier in mammals, it has virtually no effect on the mammalian CNS. The minimal pharmacological activity in mammals is supported by safety studies involving systemic administration of sub-lethal doses to rabbits, mice and rats.

In further 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 and dog's surroundings are killed following contact with a treated animal. Oral studies in the rat show imidacloprid to be absorbed rapidly from the gastrointestinal tract. Almost complete absorption (95%) occurs within 48 hours. Peak plasma concentrations are observed within 2.5 hours following administration. Tissue distribution is also rapid with the lowest levels recorded in the brain. The active ingredient undergoes extensive metabolism with only 10-16% remaining as parent compound. Almost complete (96%) elimination occurs within 48 hours, approximately 75% being removed by the kidneys and 21% with the faeces. The solution is indicated for cutaneous administration. Following topical application, the product is quickly distributed over the animal. Acute dermal studies in the rat and target animal overdose and serum kinetic studies have established that systemic absorption is very low, transient and not relevant for clinical efficacy. This has been further demonstrated by a study in which fleas were not killed after having fed on previously treated animals once the animal's skin and fur had been cleaned of all active material.

Marketing Authorisation Number:

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

Vm 00010/4117

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

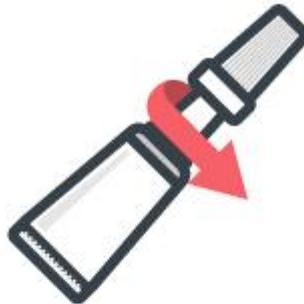
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Advantage 100 Spot-On Solution for Dogs
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Advantage 250 Spot-On Solution for Dogs
Vm 00010/4166
Advantage 400 Spot-On Solution for Dogs
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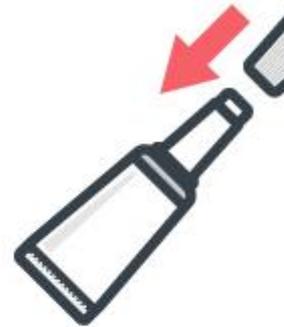
How to use Advantage Spot On Flea treatment



1. Get the pipette and hold it upright and away from you



2. Twist to remove the cap



3. Turn the cap up down and place other end over the tip at the top of the pipette



4. Part the fur at the back of your pet's neck



5. Place the tip of the tube on the skin and squeeze firmly to apply the treatment