SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bob Martin Double Action Spot-On Solution 40 mg for Cats & Small Dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance	**mg per 0.4 ml tube**
Imidacloprid	40
Excipients	
Butylated hydroxytoluene (Antioxidant)	0.4
Benzyl alcohol	332.8

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Spot-on solution.
Clear yellow to brownish solution.

4. CLINICAL PARTICULARS

4.1 Target species

For cats & dogs

4.2 Indications for use, specifying the target species

For the prevention and treatment of flea infestations on cats and dogs of less than 4 kg body weight.

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

For dogs of 4 kg bodyweight and greater, use the appropriate Bob Martin Double Action Spot-On product (see section 4.9).

4.3 Contraindications

Do not treat unweaned puppies or kittens of less than 8 weeks of age.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings for each target species

If signs of disease persist or appear, consult a veterinary surgeon.

4.5 Special precautions for use

i. Special precautions for use in animals

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.

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.

ii. Special precautions to be taken by the person administering the medicinal product to animals

People with known hypersensitivity to Imidacloprid should avoid contact with the veterinary medicinal product
This product contains benzyl alcohol and may cause skin sensitisation or transient skin reactions (for example, irritation, tingling).
Do not get the product on your skin or in your eyes or mouth.
If you get the product on your skin, wash it off with soap and water.
If you get the product in your eyes, wash your eyes thoroughly with clean water.
If the product causes any irritation to your skin or eyes that is persistent, contact your doctor.
If the product is swallowed, contact your doctor immediately.
Do not eat, drink or smoke whilst using this product.
Wash hands thoroughly after use.
After application, do not stroke or groom animals until application site is dry.
Keep stored tubes in the original packaging until ready to use. In order to prevent children from getting access to used tubes, dispose of used tubes immediately.

iii. Other precautions

The solvent in Bob Martin Double Action Spot-On may mark certain materials including leather, fabrics, plastics and finished surfaces. Allow application site to dry before permitting contact with such materials.

Imidacloprid is toxic to aquatic organisms. To avoid adverse effects on aquatic organisms, treated dogs should not be allowed to enter surface water for 48 hours after treatment.

4.6 Adverse reactions (frequency and seriousness)

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 also section 4.9 *Amount(s) to be administered and administration route*).

In very rare occasions skin reactions such as hair loss, redness, itching and skin lesions may occur. Agitation and, in dogs, disorientation have also been reported. Excessive salivation and nervous signs such as incoordination, tremors and depression have been reported exceptionally.

Oral ingestion may result in other gastrointestinal signs (vomiting and diarrhoea), which have been observed very rarely, in cats, based on post-marketing data.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

4.7 Use during pregnancy, lactation or lay

No primary embryotoxic, teratogenic or reproductive toxic effects have been observed during the studies on rats and rabbits. Studies on pregnant and lactating bitches and queens together with their offspring are limited. Evidence so far suggests that no adverse effects are to be expected in these animals.

Consult your veterinary surgeon before using in pregnant or nursing animals.

4.8 Interaction with other medicinal products and other forms of interaction

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

Do not use simultaneously with other flea products which are applied directly onto the animal.

4.9 Amount(s) to be administered and administration route

Weigh your pet accurately before use and use the correct tube size.

Dosage and Treatment Schedule

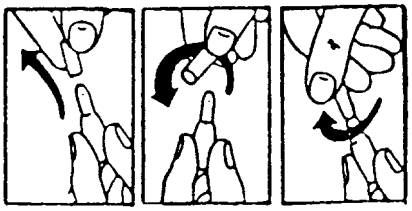
Cat/Dog	Product	Number of Tubes	mg/kg bw
Less than 4 kg bodyweight	Bob Martin Double Action Spot-On Solution 40 mg for Cats & Small Dogs	1 x 0.4 ml	Minimum of 10
Cats of 4 kg body weight and greater receive 2 tubes of Bob Martin Double Action Spot-On Solution 40 mg for Cats & Small Dogs. Dogs of 4 kg body weight and greater receive the appropriate Bob Martin Double Action Spot-On product for Dogs.			

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.

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.

Method of Administration

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



<u>Administration to the Cat</u>

Part the hair on the cat'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.
When two tubes are required for cats weighing 4 kg and over, both tubes should be applied to the same spot at the base of the skull.

Administration to the Dog

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.

General

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.

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

Poisoning following inadvertent oral uptake in either man or animals is unlikely. In this event, treatment should be symptomatic. There is no known specific antidote but administration of activated charcoal may be beneficial.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

The Active Ingredient

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.

ATC Vet Code: QP53AX17

5.1 Pharmacodynamic properties

The pharmacological properties of imidacloprid are novel. The substance has a high affinity for the nicotinergic 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 nicotinergic 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 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.

5.2 Pharmacokinetic particulars

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol
Butylated hydroxytoluene
Propylene carbonate

6.2 Incompatibilities

None known.

6.3 Shelf-life

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

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.
Store away from food drink and animal feedingstuffs.

6.5 Nature and composition of immediate packaging

Packaging style:	Blisters packs containing either 2, 3, 4 or 6 unit dose tubes.
Pack Size	Cartons containing 1, 5, 10 or 20 blisters each with 2, 3, 4 or 6 tubes. Not all pack sizes may be marketed.
Container material:	White polypropylene tube containing 0.4 ml of the product. White polypropylene cap.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

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

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.

7. MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd.
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

8. MARKETING AUTHORISATION NUMBER

Vm 00879/4128

9. DATE OF FIRST AUTHORISATION

26 March 2001

10. DATE OF LAST REVISION OF THE TEXT

November 2021

Approved: 12/11/21