SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bob Martin Double Action Spot-On Solution 400 mg for Extra Large Dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance	**mg per 4.0 ml tube**
Imidacloprid	400
Excipients	
Butylated hydroxytoluene (Antioxidant)	4.0
Benzyl Alcohol	3328.0

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

Dogs.

4.2 Indications for use, specifying the target species

For the prevention and treatment of flea infestations on dogs of 25 kg body weight and greater.

Fleas on dogs are killed within one day following treatment.
One treatment prevents further flea infestation for four weeks.

For dogs less than 25 kg body weight, use the appropriate Bob Martin Double Action Spot-On for Dogs product (see section 4.9).

4.3 Contraindications

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

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.

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

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.

iii Other precautions

The solvent in Bob Martin Double Action Spot-On Solution 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 dog licks the application site immediately after treatment. This is not a sign of intoxication and disappears within some minutes without treatment
(see also section 4.9 *Amounts 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.

4.7 Use during pregnancy, lactation or lay

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 bitches 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: fenthion, lufenuron, milbemycin, febantel, pyrantel and praziquantel. 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

Dog (kg bw)	Product	Number of Tubes	mg/kg bw
25 to less than 40	Bob Martin Double Action Spot-On Solution 400 mg for Extra Large Dogs	1 x 4.0 ml	maximum of 16
40 and greater	Bob Martin Double Action Spot-On Solution 400 mg for Extra Large Dogs	2 x 4.0 ml	maximum of 20
Dogs of less than 4 kg body weight receive 1 tube Bob Martin Double Action Spot-On Solution 40 mg for Small Cats & Small Dogs (0.4 ml). Dogs of 4 kg to less than 10 kg body weight receive 1 tube Bob Martin Double Action Spot-On Solution 100 mg for Medium Dogs (1.0 ml). Dogs of 10 kg to less than 25 kg body weight receive 1 tube Bob Martin Double Action Spot-On Solution 250 mg for Large Dogs (2.5 ml).			

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.

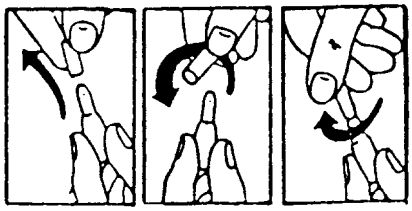
The product remains effective if the animal becomes wet, for example after swimming or exposure to heavy rain. However, in cases of frequent swimming or bathing re-treatment may become necessary,

depending on the presence of fleas in the environment. In these cases do not re-treat more frequently than once weekly.

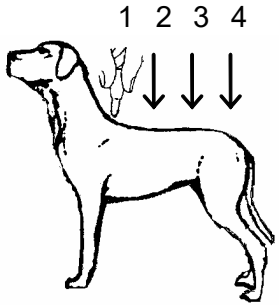
Method of Administration

For dogs of 25 to less than 40 kg body weight only:

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.



The dog should be standing for easy application. The entire contents of the tube should be applied evenly to three or four spots on the top of the back 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 to expel a portion of the contents directly onto the skin.

For Dogs of 40 kg body weight and greater only:

Remove two tubes from the package. Using the techniques described above apply the entire contents of each tube evenly to three or four spots all located at different application sites along the dog's backline from the shoulder to the base of the tail.

For all dogs:

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.

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.

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

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

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 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.

5.2 Pharmacokinetic particulars

The product is indicated for cutaneous administration. Following topical application in dogs, the solution 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 the 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
Propylene carbonate
Butyl hydroxytoluene

6.2 Incompatibilities

None known.

6.3 Shelf-life

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

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Packaging style	Blister packs containing either 2, 3, 4 or 6 unit dose tubes.
Pack Size	Carton contains 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 4.0 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.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

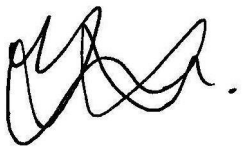
Vm 00879/4129

9. DATE OF FIRST AUTHORISATION

03 April 2007

10. DATE OF LAST REVISION OF THE TEXT

October 2020



Approved: 21 October 2020