

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bob Martin Permethrin Dog Spot On Solution 744 mg

[Permethrin 744mg/ml spot-on for dogs]

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

<b>Active Substance</b>	per ml
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Permethrin (cis: trans 25:75)	744mg
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### **Excipient**

Methyl diglycol	to 1ml
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## 3. PHARMACEUTICAL FORM

Spot-on solution.

An amber coloured, clear solution.

## 4. CLINICAL PARTICULARS

### 4.1 Target species

Dog

### 4.2 Indications for use, specifying the target species

Infestations of dog ectoparasites sensitive to permethrin:

Elimination of fleas (*Ctenocephalides felis*) and ticks (*Ixodes ricinus* and *Rhipicephalus sanguineus*).

Prevention of flea (*Ctenocephalides felis*) infestations for 4 weeks.

The product has a persistent acaricidal efficacy for up to 4 weeks against tick (*Ixodes ricinus* and *Rhipicephalus sanguineus*) infestations.

### **4.3 Contraindications**

- i) Do not use on puppies under 3 months of age.
- ii) Do not use in puppies and dogs under 2kg.
- iii) The safety of the product has not been demonstrated in pregnant and lactating bitches. Do not use in pregnant and lactating bitches. (see Section 4.7).
- iv) Do not administer to dogs with known hypersensitivity to any of the ingredients.
- v) Do not use on sick or convalescing animals and in cases of cutaneous lesions.
- vi) **DO NOT USE ON CATS.** This product is extremely poisonous to cats and could kill them. To prevent cats from being accidentally exposed to the product, keep treated dogs away from cats for 72 hours after the treatment. It is important to ensure that cats do not groom the site of application on a dog, which has been treated with this product. Seek veterinary advice immediately if this occurs.

### **4.4 Special warnings**

When first applied to the dog the product may cause a transient slightly greasy patch to develop at the site of application; in the case of animals with very light-coloured coats this may be yellowish in colour.

If there is more than one dog in the household, they must all be treated. Cats in the same household should be treated with a product registered for cats.

Avoid frequent swimming or shampooing of the animal because there may be a reduction of the effectiveness.

Fleas from pets often infest animal baskets, bedding and regular resting areas, such as carpets and furnishings, which should be treated with a suitable insecticide and vacuumed regularly.

If signs of disease persist or appear consult your veterinary surgeon.

#### 4.5 Special precautions for use

i) Special precautions for use in animals

Dogs should be prevented from licking the site of application.

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

Wash hands after use. Avoid direct contact with hands. Wash off splashes immediately. Avoid contact with eyes. If splashed in the eye, wash with plenty of clean running water.

It is recommended to wear gloves during application. Users making multiple applications, for example in a kennels, should wear protective gloves made of neoprene or nitrile and of minimum thickness 0.3mm.

Treated dogs should not be allowed close to sources of open flame until the substance has dried. Do not smoke while applying the product.

Do not handle the area of application for 3-6 hours after treatment. Persons with known hypersensitivity to pyrethroid insecticides should avoid handling the product.

In humans, handling permethrin can produce a tingling in the fingers that occurs within 1 – 2 hours.

In case of accidental ingestion, seek medical advice. In cases of persistent skin irritation and / or eye irritation, seek medical advice.

It is preferable to treat during the evening.

Treated dogs should not be allowed to sleep with people, particularly children.

iii) **Other precautions**

Treated dogs should not be allowed to go swimming for twelve hours after treatment.

#### 4.6 Adverse reactions (frequency and seriousness)

i) A mild, localised irritation at the site of application may commonly occur, and resolves within 48 hours. Transient alopecia at the application site may also occur.

ii) Transient hyperaesthesia and scratching of the site of application may occur after treatment with the product.

iii) In rare cases, acute central nervous system intoxication and gastro-intestinal disturbances may also be reported.

#### **4.7 Use during pregnancy, lactation or lay**

Laboratory studies in rats have shown evidence of foetotoxic effects. Do not use in pregnant and lactating bitches.

#### **4.8 Interaction with other medicinal products and other forms of interaction**

None known.

#### **4.9 Amounts to be administered and administration route**

For external use only.

For dogs weighing from 2kg up to 15 kg: Part coat between shoulder blades until skin is visible. Squeeze 1 ml of Bob Martin Permethrin Dog Spot On directly onto the skin. Avoid application to fur. Avoid the contents coming into direct contact with fingers.

For dogs weighing more than 15 kg and up to 30kg: Part coat between shoulder blades until skin is visible. Squeeze 1 ml of Bob Martin Permethrin Dog Spot On directly onto the skin. Avoid application to fur. Avoid the contents coming into direct contact with fingers. Apply 1 ml of Bob Martin Permethrin Dog Spot On in a similar manner at the base of the tail.

Do not retreat at intervals less than 14 days.

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

Twice the recommended dose does not produce adverse effects in adult dogs. Clinical signs of overdose are typical of pyrethroid toxicity. These include hypersalivation, diarrhoea, muscle tremors and hyperaesthesia. In severely affected animals hypothermia or hyperthermia, dyspnoea and convulsions may be observed. If signs of overdose develop, the dog should be bathed in a non-insecticidal shampoo and symptomatic treatment administered by a veterinary surgeon. There is no specific antidote for pyrethroid poisoning.

#### **4.11 Withdrawal period(s)**

Not applicable [for non-food producing animals only].

### **5. PHARMACOLOGICAL PROPERTIES**

Permethrin is a synthetic pyrethroid. It is in the ectoparasiticide pharmacotherapeutic group QP53, and bears the ATC Vet Code QP53AC04.

## **5.1 Pharmacodynamic properties**

The mechanism of insecticidal activity involves inhibition of the inactivation of sodium channels and the activation of potassium conductance at the neurone axon level. This results in prolonged action potentials, repetitive neuronal firing after a single stimulus and spontaneous trains of action potentials, leading to paralysis and death of the insect.

## **5.2 Pharmacokinetic particulars**

Permethrin can be absorbed to a limited extent after topical application to human and animal skin.

Metabolism of permethrin in mammals is by ester cleavage, by hydroxylation of the geminal dimethyl group in the acid or the phenoxy group in the alcohol, and by conjugation of the resulting carboxylic acids and phenols. Permethrin isomers, their hydrolysis products and metabolites are excreted rapidly and are not retained in tissue to an unusual extent.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Methyl diglycol

### **6.2 Incompatibilities**

Not applicable

### **6.3 Shelf life**

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

### **6.4. Special precautions for storage**

- i) Do not store above 25°C.
- ii) Protect from light.
- iii) Do not refrigerate.

## **6.5 Nature and composition of immediate packaging**

The primary container is an opaque, white polypropylene, 2 ml capacity snip-off nozzle tube. 1 ml of fill is contained within each tube. The secondary container is a clear PVC blister, heat sealed to a printed, gloss finish cardboard backing card.

Small Dogs: Pack size: 1 x 1ml, 2 x 1 ml, 3 x 1ml, 4 x 1ml  
Large Dogs: Pack size: 2 x 1ml, 4 x 1ml, 6 x 1ml, 8 x 1ml

Not all pack sizes may be marketed.

## **6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products**

- i) Any unused product or waste material should be disposed of in accordance with national requirements.
- ii) Extremely dangerous to fish and aquatic organisms. Bob Martin Permethrin Dog Spot On 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 packaging. The product is also very toxic to honeybees.

## **7. MARKETING AUTHORISATION HOLDER**

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## **8. MARKETING AUTHORISATION NUMBER**

Vm 00715/4077

## **9. DATE OF RENEWAL OF AUTHORISATION**

29 October 2008

## **10. DATE OF REVISION OF THE TEXT**

22 July 2010

## **PROHIBITION OF SALE, SUPPLY AND/OR USE**

Not applicable.