

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT, INCLUDING ITS STRENGTH AND PHARMACEUTICAL FORM:

Bob Martin Flea and Tick Spot On Solution 744mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Active Substance(s)	per ml
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Permethrin (cis: trans 25:75)	744mg
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For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM:

Spot-on solution.

Clear, pale, amber solution.

4. CLINICAL PARTICULARS:

4.1 Target species

Dogs

4.2 Indications for use, specifying the target species

For the treatment and control of fleas and ticks on dogs. Bob Martin Flea and Tick Spot On kills fleas and ticks and provides protection from re-infestation for up to four weeks. Published data for an essentially similar product demonstrate a flea adulticidal efficacy of approximately 98%, 24 hours post treatment. This would inhibit the production of eggs by the female flea, thereby breaking the flea life cycle.

4.3 Contra-Indications

- i) Do not use on puppies under 2 weeks of age.
- ii) DO NOT USE ON CATS

4.4 Special warnings for each target species

CAUTION: EXTREMELY POISONOUS TO CATS. It is important that cats do not come into contact with this product as it could kill them. To prevent cats from being accidentally exposed to the product, you must keep treated dogs away from cats for 72 hours after the treatment.

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

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

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

4.5 Special precautions for use

i) Special precautions for use in animals

Treated dogs should not be allowed close to sources of open flame until the substance has dried.

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

Wash hands after use.

Avoid direct contact with hands. Wash off any 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.

Do not smoke when applying the product.

Do not handle the area of application for 6 hours after treatment.

Persons with known hypersensitivity to pyrethroid insecticides should avoid handling the product. In humans, handling permethrin can produce a cutaneous paraesthesia with a latency period of 1 – 2 hours.

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

It is preferable to treat during the evening.

Treated animals should not be allowed to play or sleep with people, particularly children for 8 hours immediately following treatment.

Keep away from food and drink, including animal feeding stuffs.

iii) Other precautions

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

Do not allow your dog near to varnished, polished, plastic or leather surfaces until application site is completely dry. Take particular care around leather upholstery.

4.6 Adverse reactions (frequency and seriousness):

In a small minority of dogs, a transient, localised irritation at the site of the application has been reported. If this occurs, bathe the dog with a detergent-based shampoo and consult a vet.

4.7 Use during pregnancy, lactation or lay:

Studies with rats have demonstrated that permethrin has a minor effect on mammalian reproduction during pregnancy, indicated by increases in foetal resorption. Limited studies with pregnant and nursing canine bitches have not shown any evidence of toxicity to the pups.

4.8 Interaction with other medicinal products and other forms of Interaction:

None known.

4.9 Amounts to be administered and administration route:

For dogs weighing up to 15 kg: Part coat between shoulder blades until skin is visible. Squeeze 1 ml of Bob Martin Flea and Tick 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: Part coat between shoulder blades until skin is visible. Squeeze 1 ml of Bob Martin Flea and Tick 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 Flea and Tick Spot On in a similar manner at the base of the tail.

Clinical trials indicate that up to 4 weeks protection may be achieved following each application.

The 1 x 1ml, 3 x 1ml and 4 x 1ml pack sizes are specifically targeted at small dogs (up to 15kg) and puppies. The 2 x 1ml, 6 x 1ml and 8 x 1ml packs are targeted at dogs above 15kg.

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

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.

5. PHARMACOLOGICAL PROPERTIES:**5.1 Pharmacodynamic properties**

Permethrin is an insecticide. 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.

Permethrin is a pyrethroid insecticide. Unlike the earlier pyrethroids and natural pyrethrins, permethrin has good photostability and hence residual efficacy.

5.2 Pharmacokinetic properties

No specific pharmacokinetic studies have been performed with the product. Literature reports indicate that permethrin has low bioavailability (<1.0%) via the dermal route.

ATC Vet Code: QP53AC04

6. PHARMACEUTICAL PARTICULARS:**6.1 List of excipients**

Methyl Carbitol

6.2 Incompatibilities

None known.

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

1 x 1ml, 2 x 1 ml, 3 x 1ml, 4 x 1ml, 6 x 1ml, 8 x 1ml opaque, white polypropylene tube with snip-off nozzle and heat sealed closure.

Not all pack sizes may be marketed.

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

Any unused product or waste material should be disposed of in accordance with national requirements. Extremely dangerous to fish and aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or packaging.

7. MARKETING AUTHORISATION HOLDER:

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8. MARKETING AUTHORISATION NUMBER:

Vm 00715/4078

9. DATE OF THE FIRST AUTHORISATION:

13 January 2003

10. DATE OF REVISION OF THE TEXT:

January 2009