

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ticacyl Spot On Solution 744mg for small dogs up to 15kg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tube contains:

Active Substance(s)

Permethrin (cis: trans 25:75) 744mg

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:

Domestic Dog

4.2 Indications for use, specifying the target species:

For treatment and control of ticks and fleas on dogs. Kills ticks and fleas and provides protection from reinfestation for up to four weeks.

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

For external use only.

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

Avoid the drops coming into contact with your fingers. Wash off any splashes immediately with plenty of clean water. Avoid contact with eyes. In case of accidental eye contact, rinse with clean, fresh water. If eye irritation persists, seek medical advice. Wash hands and exposed skin with soap and water after use.

Users making multiple applications, such as in kennels, should wear protective gloves (neoprene or nitrile, 0.3mm minimum thickness). If you feel unwell as a result of handling this product, you should consult your doctor. Do not handle the area of application for 6 hours following treatment. Treated animals should not be allowed to play or sleep with people, particularly children, for 8 hours immediately following treatment. It is preferable to treat during the evening. 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.

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

The product is marketed in packs targeted at dogs weighing up to 15kg bodyweight (translucent purple-pink tube, 1ml fill).

For dogs weighing up to 15 kg: Use product contained within translucent purple-pink tube (744mg permethrin / 1ml). Snip off the tip of the tube to open. Part coat between shoulder blades until skin is visible. Squeeze 1ml of Bob Martin Dog Spot On Solution 744mg directly onto the skin. Avoid application to fur. Avoid the contents coming into direct contact with fingers.

For dogs weighing more than 15 kg: Use Bob Martin Dog Spot On Solution 1488mg.

The interval between treatment will depend upon the severity of parasite challenge. Clinical trials indicate that up to 4 weeks protection may be achieved following each application. In circumstances where dogs are severely wetted after treatment, e.g., by shampooing, the period of protection may be reduced. Bob Martin Dog Spot On Solution 744mg may be safely applied at intervals of not less than 7 days.

The 1 x 1ml and 3 x 1ml (translucent purple-pink tube) pack sizes are specifically targeted at small dogs (up to 15kg) and puppies.

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

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.

5.3 ATCvet 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.
- iv) Do not remove from blister until required for use.

6.5 Nature and contents of immediate packaging:

1 x 1ml, 2 x 1ml, 3 x 1ml and 4 x 1ml translucent pink polypropylene (random co-polymer) tube with snip-off tip with crimped 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 veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements. Extremely dangerous to fish and aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or packaging.

7. MARKETING AUTHORISATION HOLDER:

Bob Martin (UK) Ltd.
Wemberham Lane
Yatton
Somerset
BS49 4BS

8. MARKETING AUTHORISATION NUMBER:

Vm 00715/4054

9. DATE OF FIRST AUTHORISATION:

Date: 13 April 1993

10. DATE OF REVISION OF THE TEXT:

Date: December 2013

 19 December 2013