

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Canac Flea and Tick Spot-on solution 742 mg

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each 1 ml dose contains:

**Active substance:**

Permethrin 25:75 cis:trans (742 mg)

**Excipients:**

For the full list of excipients, see section 6.1.

### **3. PHARMACEUTICAL FORM**

Spot-on solution

Amber, clear solution.

### **4. CLINICAL PARTICULARS**

#### **4.1 Target species**

Dogs

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

For the control of flea and tick infestations on dogs, for a period of up to 4 weeks.

#### **4.3 Contraindications**

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 that has been treated with this product.

Seek veterinary advice immediately if this occurs.

Do not use on dogs less than 2 weeks of age.

#### **4.4 Special warnings for each target species**

None

If your dog becomes unwell or shows any unusual signs or irritation, then you should consult your veterinary surgeon taking this pack, and if possible the vials with you.

#### **4.5 Special precautions for use**

None

If your dog becomes unwell or shows any unusual signs or irritation, then you should consult your veterinary surgeon taking this pack, and if possible the vials with you.

- (i) Special precautions for use in animals  
For external use only.  
Do not apply to the dog's fur or massage into the skin.
  
- (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, 0.3 mm 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, when children are in bed.  
  
Keep away from food and drink, including animal feeding stuffs.
  
- (iii) Other precautions  
Treated dogs should not be allowed to swim for at least 12 hours after treatment.

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

Occasionally a sensitive animal may experience localised skin irritation, in which case bathe dog with a mild, non-insecticidal shampoo.

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

Not for use on lactating bitches with puppies less than 2 weeks of age.

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

Do not administer any other flea control products to your dog during the 4-week period of protection.

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

For dogs weighing up to 15 kg (33 lb):

1. Open the vial immediately prior to use, by holding upright and twisting the cap off, taking care not to squeeze the vial.
2. Part the dog's coat to expose the skin between the shoulder blades, at the nape of the neck.
3. Squeeze the entire contents of one vial on to the exposed skin.  
For dogs weighing over 15 kg (33 lb):  
Apply as 1-3, above, then
4. Open the second vial and apply by parting the dog's coat at the base of the tail, then squeeze the entire contents of the second vial onto the exposed skin.  
Re-treat after 28 days if any reinfestation is apparent. If the dog's coat is subsequently wetted, such as shampooing, the 4-week period of protection may be reduced.  
The drops can safely be applied at intervals of not less than 7 days.

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

Not applicable given pack size and tolerance in target species.

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

Not applicable to companion animals.

### **5. PHARMACOLOGICAL PROPERTIES**

Pharmacotherapeutic group: Ectoparasiticides for topical use, incl. insecticides  
ATCvet code: QP53AC04

#### **5.1 Pharmacodynamic properties**

Permethrin is a contact ectoparasiticide acting on the sodium channel. It attacks the peripheral nervous system and in particular the motor nerve terminals in the central nervous system. Broadly speaking, permethrin causes knockdown in arthropods, inducing loss of coordination, spasms, tremors and ultimately, death. When topically administered, the solution will rapidly disperse across the surface of the skin, by virtue of the carrier having a high flash point coupled with a relatively low viscosity and a very low vapour pressure. This mobility of the solution, in combination with capillary action through the coat and across the skin, together with the natural movement of the animal, ensures adequate dispersion.

Given that a high flea mortality was achieved one day after topical administration of the solution, this indicates good coverage of the individual animals by the insecticide.

#### **5.2 Pharmacokinetic particulars**

If permethrin is orally administered to mammals it is rapidly metabolised and almost completely excreted via urine or faeces within a short period of time. The trans isomer is eliminated faster than the cis isomer, it being the more susceptible of the two to esterase attack. The major metabolic reactions are ester hydrolysis, ester cleavage, oxidation and conjugation. Permethrin does not have a tendency to accumulate in tissues. None of the metabolites of permethrin show a higher acute toxicity than the base permethrin. Given that this product is administered externally, absorption rates are considerable lower than when orally administered.

## **6. Pharmaceutical particulars**

### **6.1 List of excipients**

Methyl carbitol

### **6.2 Major Incompatibilities**

Do not administer other methods of on-animal flea control during treatment.

### **6.3 Shelf life**

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

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

#### **Do not store above 25°C**

Protect from direct sunlight

Do not freeze

Do not refrigerate

Do not remove the vial from the pack until ready to use

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

White polypropylene single-use vial, 2 ml capacity to give 1 ml dose.

Filled from base and heat-sealed. Batch number and expiry date embossed onto base seal. Twist off cap to administer contents.

Final presentation to be one, two, three or six vials, each in a rigid plastic blister, attached to a blister card.

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 in accordance with local requirements.

**EXTREMELY DANGEROUS TO FISH** and aquatic life.

Do not contaminate ponds, waterways or ditches with the product or empty packaging.

## **7. MARKETING AUTHORISATION HOLDER**

Sinclair Animal and Household Care Ltd.  
Ropery Road  
Gainsborough  
Lincolnshire

DN21 2QB

**8. MARKETING AUTHORISATION NUMBER**

Vm 16516/4083

**9. DATE OF FIRST AUTHORISATION**

12 November 1998

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

May 2019

Approved: 17 May 2019

