

## **SUMMARY OF PRODUCT CHARACTERISTICS**

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

Armitage Pet Care flea and tick drops for dogs 702mg Spot-on solution

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

Each vial contains:

<b>Active substance(s)</b>	<b>mg</b>
Permethrin cis:trans 25:75	702

For full list of excipients, see section 6.1

### **3. PHARMACEUTICAL FORM:**

Spot on solution

A clear pale yellow – brown odourless liquid.

### **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. 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 exposed to the product keep treated dogs away from cats for 72 hours after the treatment.

Ensure that cats do not groom the site of application on a dog. Seek veterinary advice immediately if this occurs.

Do not use if your dog is sick or recovering from an illness.

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

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

If the dog's coat is subsequently wetted, such as when shampooing, the 4 weeks period of protection may be reduced.

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

##### **(i) Special precautions for use in animals**

For external use only.  
Do not massage into the dog's skin.  
Do not apply to the dog's fur.

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.

##### **(ii) Special precautions for the person administering the veterinary medicinal product to animals.**

Avoid the drops coming into contact with your fingers.  
Avoid contact with skin and eyes.  
Wash off any splashes immediately with plenty of clean water.  
Wash your hands with soap and water after applying the drops.  
In case of accidental eye contact, rinse with clean, fresh water. If eye irritation persists, seek medical advice.  
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 see your Doctor.  
Treated animals should not be allowed to play or sleep with people, particularly children, for 8 hours immediately following treatment.  
Do not handle the area of application for 6 hours following treatment

##### **(iii) Other precautions**

Treated dogs should not be allowed to go swimming for 12 hours following treatment.

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

Rarely, transient, localized irritation at the site of application may occur.  
Should this occur, bathe the dog with mild shampoo and seek veterinary advice.

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

Do not 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 Amount(s) to be administered and administration route**

For dogs weighing up to 15kg (33lb): - USE 1 VIAL

1. Only 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 onto the exposed skin.

For dogs weighing over 15kg (33 lb): - USE 2 VIALS

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 re-infestation is apparent.

If the dog's coat is subsequently wetted, such as when shampooing, the 4 weeks 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**

No adverse reactions were seen up to three times the recommended dose.  
Do not exceed the stated dose.

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

Not applicable.

### **5. PHARMACOLOGICAL PROPERTIES**

**Pharmacotherapeutic group:** antiparasitic agent

**ATC Vet 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.

## **5.2 Pharmacokinetic properties**

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 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.

If Permethrin is orally administered to mammals it is rapidly metabolized 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 considerably lower than when orally administered.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

D-limonene  
Polyoxypropylene 15 stearyl ether

### **6.2 Incompatibilities**

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

### **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 (or refrigerate).  
Do not remove the vial from the pack until ready to use.

**6.5 Nature and composition of immediate packaging**

1.5ml white opaque polypropylene unit dose tube with heat sealed closure. Rigid plastic blister attached to a backing card containing either 1,2,3,4 or 6 tubes.  
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, if appropriate**

Extremely dangerous to fish, other aquatic life and reptiles.  
Do not contaminate aquaria, ponds or other waterways with the product or packaging.  
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**

Mr H I Moulds and Mrs S J Moulds  
10 Brown Moor Road  
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**8. MARKETING AUTHORISATION NUMBER(S)**

Vm 20205/4003

**9. DATE OF FIRST AUTHORISATION**

Date: 20.8.2003

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

May 2009