

SUMMARY OF PRODUCTS CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Easi-drop flea and tick drops for dogs 742mg cutaneous solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Qualitative composition

Permethrin cis:trans 25;75

Quantitative composition

Permethrin 742mg/ml

For full list of excipients, see Section 6.1

3. PHARMACEUTICAL FORM

Cutaneous solution.

A clear pale amber 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 Contra-indications

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 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.

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.
It is preferable to treat during the evening, when children are in bed.
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.
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 dogs 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 (33lb): 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.

Not to 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

Methyl carbitol

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 backing card until ready to use.

6.5 Nature and composition of immediate packaging

White polypropylene single-use vial, 2ml capacity to give a 1ml dose. The base is heat sealed. Batch number and expiry dates are either embossed onto the base seal or printed in ink on the vial. The cap is a twisted off to administer contents and is not re-closable.

Presentation: one, two, three or six vials, encased in rigid plastic blisters,

attached to a backing card.
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 and aquatic life.
Do not contaminate ponds, waterways or ditches with the product.
Dispose of unused product and empty containers in accordance with guidance from your local waste regulation authority.

7. MARKETING AUTHORISATION HOLDER

Mr H I Moulds and Mrs S J Moulds
10, Brown Moor Road
Stamford Bridge
York
YO41 1PG

8. MARKETING AUTHORISATION NUMBER(S)

Vm 20205/4000

9. DATE OF FIRST AUTHORISATION

Date: 21.5.1999

10. DATE OF REVISION OF THE TEXT

Date: May 2011