

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pets with Wilko Dog Flea Drops, 65% w/w, Cutaneous solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

<u>Active substance</u>	<u>% w/w</u>
Permethrin 25:75 cis:trans pure	65.0

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Cutaneous solution

4. CLINICAL PARTICULARS

4.1 Target species

Dogs

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. 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 tubes, with you.

4.5 Special precautions for use

(i) Special precautions for use in animals

None

(ii) Special precautions to be taken by the person administering the 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.

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 sleep with people, particularly children, for the 8 hours immediately following treatment.

Do not handle the area of application for 3-6 hours following treatment.

Keep away from food and drink.

(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-month period of protection.

4.9 Amounts to be administered and administration route

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

1. Open the tube immediately prior to use, by holding upright and twisting the cap off, taking care not to squeeze the tube.

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 tube on to the exposed skin.

For dogs weighing over 15kg (33lb):

Apply as 1-3, above, then

4. Open the second tube and apply by parting the dog's coat at the base of the tail, then squeeze the entire contents of the second tube 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 periods for the various foodstuffs, including those for which the withdrawal period is zero

Not applicable to companion animals.

5. PHARMACOLOGICAL PROPERTIES

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.

5 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

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 tube from the pack until ready to use

6.5 Nature and contents of immediate packaging

White polypropylene single-use tube, 2ml capacity to give 1ml dose. Filled from base and heat-sealed. Batch number and expiry date embossed onto base seal. Twist off cap to administer contents. 1ml of ectoparasiticide solution, comprises 65%w/w Permethrin 25:75 cis:trans pure (synthetic pyrethroid insecticide), in a methyl carbitol solvent. Final presentation to be two tubes, each in a rigid plastic blister, attached to a blister card.

6.6 Special precautions for the disposal of unused veterinary medicinal products 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 or empty packaging.

7. MARKETING AUTHORISATION HOLDER

Sinclair Animal and Household Care Ltd
Ropery Road
Gainsborough
Lincolnshire
DN21 2QB

8. MARKETING AUTHORISATION NUMBER

Vm 16516/4002

9. DATE OF THE FIRST AUTHORISATION

19 April 2000

10. DATE OF REVISION OF THE TEXT

July 2021

Approved 23 July 2021

A handwritten signature in black ink, appearing to read "Hunter.", is written below the approval date. The signature is stylized and includes a vertical line to the left of the name.