

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SINERGEL PERMETHRIN 1430 MG SPOT-ON SOLUTION FOR DOGS

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each pipette of 2ml contains:

Active substance:

Permethrin (40:60).....1430 mg

Excipients:

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Spot-on solution

Yellow solution

4. CLINICAL PARTICULARS

4.1 Target species

Dogs (15 – 30 kg)

4.2 Indications for use, specifying the target species

Treatment and prevention of external parasites infestations in dogs caused by fleas (*Ctenocephalides canis*, *Ctenocephalides felis*) and ticks (*Rhipicephalus sanguineus*). The veterinary medicinal product prevents infestations for up to 4 weeks following administration.

One treatment provides an insecticidal effect for 3 weeks against mosquitoes (*Aedes aegypti*).

One treatment provides a repellent effect for one week against sand flies (*Phlebotomus perniciosus*).

4.3 Contraindications



Do not use in cats. This product is extremely poisonous to cats and could kill them. Do not use in dogs less than 2 weeks old. Do not use in case of hypersensitivity to the active substance or to any of the excipients.

See also section 4.5. Special precautions for use in animals.

Do not use in case of extended cutaneous injuries.

4.4 Special warnings for each target species

There may be an attachment of single ticks or bites by single sand-flies or mosquitoes. For this reason, the transmission of infectious diseases by these parasites cannot be excluded if conditions are unfavorable.

For optimal control of flea infestation in multi-pet household, all dogs and cats in the household should be treated with a suitable insecticide.

Fleas from pets often infest the animal's basket, bedding and regular resting areas such as carpets and soft furnishings which should be treated, in cases of massive infestation and at the beginning of the control measures, with a suitable insecticide and vacuumed regularly.

During the period of expected efficacy, ticks will be killed and fall off the host within 48 hours of infestation, usually without having had a blood meal. However, the attachment of single ticks may occur after treatment and therefore the transmission of infectious diseases by ticks cannot be excluded. Once dead, ticks will often drop off the animal, but any remaining ticks can be removed carefully.

The veterinary medicinal product can be safely applied at intervals of at least seven days. In the case that the treated dogs is widely wet (for example, if a dog requires a shampoo, etc.), the protection period could be reduced.

Parasite resistance to an ectoparasiticide may develop following frequent, repeated use of this ectoparasiticide or another one of the same chemical class.

4.5 Special precautions for use

Special precautions for use in animals

Care should be taken to avoid the content of the pipette coming into contact with the eyes or mouth of dogs. In particular, oral uptake due to the licking of the application site by treated or in-contact animals should be avoided.

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 of a dog that has been treated with this product. Seek veterinary advice immediately if this occurs.

This product is extremely poisonous to cats and could be fatal due to their unique physiology that is unable to metabolise permethrin. In the case of accidental dermal exposure, wash the cat with shampoo or soap, and seek veterinary advice (see section 4.3: contraindications).'

In animal of less than 2 kg the product should be used only after a benefit/risk assessment by the veterinarian.

Consult the veterinarian before using the veterinary medicinal product on sick and debilitated dogs.

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

This product can cause transient skin and eye irritation.

Avoid contact between the product and skin, eyes or mouth.

People with known skin hypersensitivity to pyrethroids should avoid contact with the veterinary medicinal product.

Treated dogs should not be handled especially by children until the application site is dry.

Therefore, animals should not be treated during the day, but should be treated in the early evening.

Recently treated dogs should not be allowed to sleep with their owner, especially children.

Do not eat, drink or smoke during application.

Wash hands thoroughly after use.

In case of accidental spillage onto skin, wash off immediately with soap and water.

If the product gets accidentally into the eyes, they should be thoroughly rinsed with water.

If skin or eye irritation persists, or if the product is accidentally swallowed, obtain medical attention immediately and show the package leaflet to the physician.

Keep stored pipettes in the original packaging until ready to use. In order to prevent children from getting access to used pipettes, dispose of used pipettes immediately in a proper way.

Other precautions

Permethrin may adversely affect aquatic organisms. Dogs should not be allowed to swim in watercourses for 2 days after application.

4.6 Adverse reactions (frequency and seriousness)

In very rare cases, dogs can exhibit lethargy, pruritus, erythema, rash and hair loss at the point of application. If it should appear, discontinue treatment, bathing the animal and go to the vet. In very rare cases, skin sensitivity reactions can appear. If it should appear, discontinue treatment, bathing the animal and go to the vet.

In very rare cases, changes of behaviour (agitation, lethargy), gastrointestinal signs (salivation, diarrhoea, vomiting, loss of appetite) and neurological signs (ataxia, tremors, convulsions or paresis). These signs are usually transient and resolve without treatment within a few hours. If signs persist, consult a veterinarian.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Laboratory studies in rats, mice and rabbits with permethrin have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects. The safety of the product has not been established in pregnant and lactating bitches. Use only accordingly to the benefit/risk assessment by the responsible veterinarian

4.8 Interaction with other medicinal products and other forms of interaction

Do not use simultaneously with other insecticides like other pyrethroids, organophosphorus compounds or carbamates.

4.9 Amounts to be administered and administration route

Spot-on use

Animals should be weighed accurately prior to treatment.

The recommended dose is:

- 1 pipette of 2 ml for dogs weighing 15-30 kg

Method of administration:

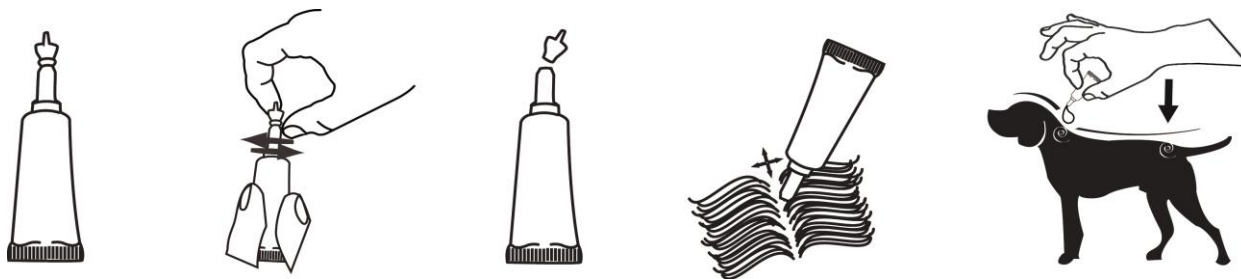
Remove one pipette from the package.

Step 1: The dog should be standing for easy application.

Hold upright. Tap the narrow part of the pipette to ensure the contents are within the main body of the pipette. Break back the snap-off top from the spot-on pipette along the scored line.

Step 2: Part the coat between the shoulder blades until the skin is visible

Step 3 (dogs from 15-30 kg): Use one pipette. The pipette content should be equally divided between two locations from the shoulder to the base of the tail.



For dermal use only. Apply only to undamaged skin.

Depending on the intensity of the infestation, the responsible veterinary surgeon may recommend repeating the treatment.

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

The risk of experiencing adverse reactions (see section 4.6) may increase with overdosing.

In the case of oral ingestion (very high doses), excitation and convulsions that can progress to paralysis and muscular fibrillation which may even lead to death by respiratory failure have been reported. Saline cathartic or active carbon suspension may be administered.

If nervous systems signs occur, treatment with anticonvulsants should be considered.

Do not administer oils and fats that promote absorption in the intestine.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Ectoparasiticides for topical use, including insecticides. Pyrethrins and pyrethroids

ATC Vet Code: QP53AC04

5.1 Pharmacodynamic properties

Permethrin, the active substance of the veterinary medicinal product, is a synthetic second-generation pyrethroid belonging to the Type I pyrethroids which produce excitation, convulsion, paralysis and death of the insect.

Type I pyrethroids (not containing an alpha-cyano group) cause an increased pronounced repetitive activity in organs and sensory nervous fibers. They act directly affecting sodium channels of the nervous membrane and cause a prolonged transient increase in sodium permeability of the membrane during excitation. The type I pyrethroids also cause repetitive pre-synaptic moderate activity.

It is active against fleas (*Ctenocephalides canis*, *C. felis*), ticks (*Rhipicephalus spp*), also it is active against mosquitoes (*Aedes aegypti*) and sand flies (*Phlebotomus perniciosus*).

5.2 Pharmacokinetic particulars

Permethrin has a topical insecticidal activity by direct contact between the insect and the active substance; the drug is not absorbed by the dog through the skin, its mechanism of action is not systemic. It is incorporated to a formulation of low volume / high concentration in which the active substance is promptly and widely spread to achieve a rapid insecticide effect.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene glycol monomethyl ether.

6.2 Major incompatibilities

Not applicable

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 36 months

6.4. Special precautions for storage

Store below 25 °C

6.5 Nature and composition of immediate packaging

2 ml white opaque spot-on pipettes of COEX- High Density Polyethylene -Extrusion material. Each pipette is packaged in a heat-sealed aluminium sachet.

The fill-volume of the pipette is 2 ml.

Package sizes: 1,2,3,4,5,6,8,10, 12, 24,30, 60, 90, 120 or 150 pipettes in carton box.

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

- Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.
- The product should not enter water courses as this may be dangerous for fish and other aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty containers.

7. MARKETING AUTHORISATION HOLDER

Sinergic Chemical S.L.
C/ Velázquez, N° 64- 4ºIzq.
28001 Madrid – Spain

- 8. MARKETING AUTHORISATION NUMBER(S)**
- 9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**
- 10 DATE OF REVISION OF THE TEXT**