

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**2 ml pipettes carton boxes**

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

SINERGEL PERMETHRIN 1430 MG SPOT-ON SOLUTION FOR DOGS  
Permethrin

**2. STATEMENT OF ACTIVE SUBSTANCES**

Permethrin 1430 mg

**3. PHARMACEUTICAL FORM**

Spot-on solution  
Yellow solution

**4. PACKAGE SIZE**

1,2,3,4,5,6, 8,10, 12, 24, 30, 60, 90, 120, 150 pipettes of 1mL in carton boxes.  
Each pipette is protected in a heat-sealed aluminum sachet.

**5. TARGET SPECIES**

Dogs

**6. INDICATION(S)**

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*).

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Read the package leaflet before use.

Spot-on use

The recommended dose is:

-1 pipette of 2 ml per dog weighing from 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 15-30kg): Use one pipette. The pipette content should be equally divided between two locations from the shoulder to the base of the tail.

#### **8. WITHDRAWAL PERIOD(S)**

#### **9. SPECIAL WARNING(S), IF NECESSARY**

For dog use only.



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.

The product should not be use in dogs weighing less than 15 kg.

Do not use in case of extended cutaneous injuries.

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.

Keep the product in the sachet until use in order to prevent children from getting access to the product. Avoid contact with skin, mouth and/or eye. Do not contact the application site until it is no longer noticeable.

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

Read package leaflet for full user safety information.

#### **10. EXPIRY DATE**

EXP {month/year}

#### **11. SPECIAL STORAGE CONDITIONS**

Store below 25 °C

Store in the original package

#### **12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Dispose of waste material in accordance with local requirements.

Disposal: read package leaflet.

#### **13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE**

For animal treatment only.

**14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

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

**16. MARKETING AUTHORISATION NUMBER(S)**

**17. MANUFACTURER’S BATCH NUMBER**

<Batch> {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**2 mL Coex Pipettes**

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

SINERGEL PERMETHRIN 1430 MG SPOT-ON SOLUTION FOR DOGS  
Permethrin

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

Permethrin 1430 mg

**3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES**

2ml pipette

**4. ROUTE(S) OF ADMINISTRATION**

Spot-on

**5. WITHDRAWAL PERIOD(S)**

**6. BATCH NUMBER**

Batch {number}

**7. EXPIRY DATE**

EXP {month/year}

**8. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**

**Aluminium blister**

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

SINERGEL PERMETHRIN 1430 MG SPOT-ON SOLUTION FOR DOGS  
Permethrin

**2. NAME OF THE MARKETING AUTHORISATION HOLDER**

SINERGIC CHEMICAL S.L.

**3. EXPIRY DATE**

EXP {month/year}

**4. BATCH NUMBER**

Batch {number}

**5. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.