

PACKAGE LEAFLET

PACKAGE LEAFLET FOR:

**PIRETRON 715 mg SPOT ON SOLUTION FOR DOGS
PIRETRON 1430 mg SPOT ON SOLUTION FOR DOGS**

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing Authorization Holder and Manufacturer responsible for batch release

QUIMICA DE MUNGUÍA S.A.
Derio Bidea, 51
48100 Munguía- Vizcaya
SPAIN

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

PIRETRON 715 mg SPOTON SOLUTION FOR DOGS
PIRETRON 1430 mg SPOTON SOLUTION FOR DOGS

Permethrin

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each pipette of 1 ml contains:

Active substance:

Permethrin (40:60).....715 mg

Excipients:

Non-aqueous vehicle....q.s. 1 mL

Yellow solution

Each pipette of 2 ml contains:

Active substance:

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

Excipients:

Non-aqueous vehicle....q.s. 2 mL

Yellow solution

4. INDICATION(S)

Treatment and prevention of external parasites in dogs caused by fleas (*Ctenocephalides canis*, *C. felis*), ticks (*Dermacentor* spp., *Rhipicephalus* spp. *Ixodes ricinus*) and lice

(*Trichodectes canis*) and supporting the control of mosquitoes (*Aedes aegypti*). The protection period is 4 weeks after the treatment with the veterinary medicinal product.

One treatment provides repellent effect for two weeks and insecticide effect for one week against sand flies (*Phlebotomus perniciosus*).

5. CONTRAINDICATIONS

Do not use in cats. The administration in cats can cause serious adverse reactions and even death could occur.

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.

6. ADVERSE REACTIONS

Signs of lethargy, pruritus, erythema, rash, and hair loss at the point of application have been observed in very rare occasions.

Skin sensitivity reactions have been reported in very rare occasions. If it occurs, withdrawal the treatment, bath the animal and consult your veterinary surgeon.

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

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.”

7. TARGET SPECIES

Dogs.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Topical application to the skin.

The recommended dose is 1 ml of the product for dogs weighing less than 15 kg and 2 ml of the product for dogs weighing over 15 Kg.

- Dogs less than 15 Kg bw.: apply the content of the 1 ml single-dose pipette between the shoulders blade.
- Dogs over 15 Kg bw.:
 - Using the 1 ml single-dose pipette: apply two doses (two pipettes), one between the shoulders blades and the other one on the base of the tail.
 - Using the 2 ml single-dose pipette: apply the content of one pipette, part between the shoulders blades and the rest on 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.

The veterinary medicinal product can be safely applied at intervals of not less than seven days.

9. ADVICE ON CORRECT ADMINISTRATION

Method of administration:

Remove one pipette from the package.

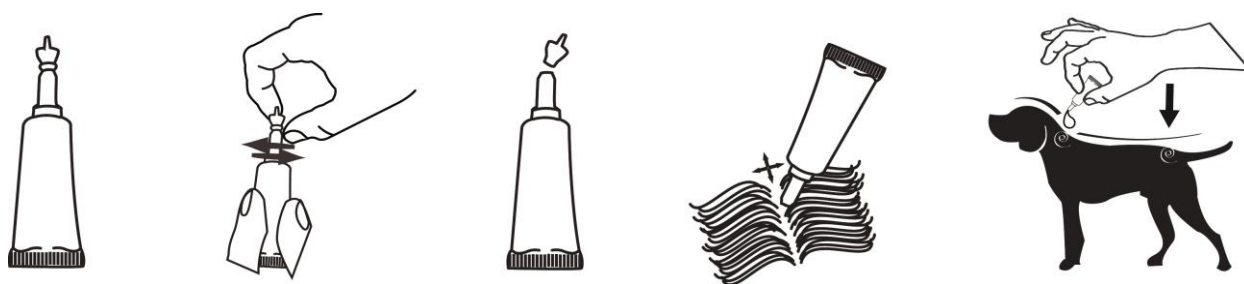
Step 1: The dog should be standing for easy application.

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 (small dogs): Place the tip of the pipette on the skin and squeeze gently applying the entire contents directly onto the skin.

Step 3 (larger dogs): Place the entire content of the pipette proportionally in two points, both located in different areas of application along the dorsal line from the shoulder to the base of the tail.



10. WITHDRAWAL PERIOD

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store below 25 C

Store in the original package

Do not use this veterinary medicinal product after the expiry date which is stated on the carton.

12. SPECIAL WARNING(S)

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 unfavourable.

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.

In the case that the treated dog is widely wet (for example, if a dog requires a shampoo, etc.), the protection period could be reduced.

Parasite resistance to an ectoparasiticide can be developed after frequent and repeated use of this ectoparasiticide or with another of the same chemical class.

Special precautions for use in animals:

For external use only.

Animals should be weighed accurately prior to treatment.

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

This product is extremely poisonous to cats and could be fatal due to the unique physiology of cats which is unable to metabolise permethrin. In case of accidental dermal exposure, wash the cat with shampoo or soap, and seek veterinary advice rapidly. To prevent cats from being accidentally exposed to the product, keep treated dogs away from cats after treatment until the application site is dry. It is important to ensure that cats do not groom the site of application on a dog, which has been treated with this product. In case of exposure of this type, seek veterinary advice immediately.

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

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

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

Wash hands thoroughly after use.

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

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

Do not eat, drink or smoke during application.

Treated animals should not be handled or played with until the application site is dry. It is therefore recommended to treat the animals in the early evening or late afternoon in order to minimise contact with the treated animal. On the day of treatment, treated animals should not be permitted to sleep with their owner, especially children.

Keep the stored pipettes in the original packaging. 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

Pregnancy and lactation

No contraindications have been described during these periods.

Interaction with other medicinal products and other forms of interaction

None known.

Overdose (symptoms, emergency procedures, antidotes):

Poisoning following overdose is unlikely due to the way of administration of the product.

The risk of experiencing adverse reactions (see section 6) may however increase with overdosing, so animals should always be treated with correct pipette size according to bodyweight.

In 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.

In case of occurrence of nervous symptoms, treat with anticonvulsants.

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste.

Ask your veterinary surgeon/ pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.>

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

To be completed in accordance with national requirements after conclusion of the renewal phase.

<15. OTHER INFORMATION>

Pipettes of 1mL and 2 mL

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

Each pipette is protected in a heat-sealed aluminum blister.

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the marketing authorisation holder.