

## **SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PIRETRON 715 mg SPOT ON SOLUTION FOR DOGS

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each pipette of 1 ml contains:

Active substance:

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

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.

### 4.2 Indications for use, specifying the target species

Treatment and prevention of external parasites infestations 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*).

### 4.3 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.

### 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.

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.

#### **4.5 Special precautions for use**

##### 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.

#### **4.6 Adverse reactions (frequency and seriousness)**

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)

#### **4.7 Use during pregnancy and lactation**

No contraindications have been described during these periods.

#### **4.8 Interaction with other medicinal products and other forms of interaction**

None known.

#### **4.9 Amounts to be administered and administration route**

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.

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.



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.

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

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

The risk of experiencing adverse reactions (see section 4.6) 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.

#### **4.11 Withdrawal period(s)**

Not applicable.

### **5. <PHARMACOLOGICAL><IMMUNOLOGICAL> 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 which produces 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 (*Dermacentor* spp., *Rhipicephalus* spp, *Ixodes ricinus*) and lice (*Trichodectes canis*), 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: 3 years.

### **6.4. Special precautions for storage**

Store below 25 C

### **6.5 Nature and composition of immediate packaging**

1mL spot-on pipettes of white opaque plastic of COEX- High Density Polyethylene -Extrusion material. Each pipette is protected in a heat-sealed aluminum blister.

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

### **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.

PIRETRON 715 mg/l spot on solution for dogs 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**

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

SPAIN

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

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of the first authorization: 8th April 2015

Date of last renewal:

**10 DATE OF REVISION OF THE TEXT**

**PROHIBITION OF SALE, SUPPLY AND/OR USE**